**Documents whose amendment is included in updated form**

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|---|---|---|---|---|
| Order | 1142 | 02.10.2025 | 06.10.2025 | |
| Order | 1356 | 19.04.2023 | 28.04.2023 | |
| Order | 1353 | 30.07.2020 | 31.07.2020 | |
| Order | 40 | 16.01.2018 | 25.01.2018 | |
| Rectif. | 487 | 28.04.2017 | 18.05.2017 | |
| Order | 487 | 28.04.2017 | 05.05.2017 | |
| Order | 387 | 31.03.2015 | 02.04.2015 | |
| Order | 1200 | 16.10.2014 | 16.10.2014 | |

**Ministry of Health**

# 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

***) Note:**
**Includes all changes made to the official document, published in the Official Gazette of Romania, mentioned in:**
**Order of the Minister of Health no. 1.142/02.10.2025 Published in the Official Gazette of Romania no. 916/06.10.2025**

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 of Romania, registered at the Ministry of Health with no. 44.495 of 22 July 2014,

Taking into account the provisions of Article $232^{1}$ of Law 95/2006 on

healthcare reform, as amended,

Taking into account the provisions of 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 of Romania, 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:**

**Art. 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**.

**Art. 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.

**Art. 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.

**Art. 4 -** The template for the application to be submitted to the Registry Office of the National Agency for Medicines and Medical Devices of Romania 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.

**Art. 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.

**Art. $5^{1*)}$** – The template of decision of the National Agency for Medicines and Medical Devices of Romania (**NAMMD**) inclusion, extension of indications, non-inclusion into or exclusion of medicinal products, addition/relocation of a reimbursed INN, marking of a reimbursed INN with (*), (**) or (**)[1] in/from the List, mentioned in Annex 6.

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*) Art. $5^1$ was introduced through Order no. 387/2015 of 2 April 2015.

**Art. 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 of Romania of Romania 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 of Romania makes decisions in accordance with provisions of this Order.

**Art. 7 -** (1) The List shall be updated, at least quarterly, for the following INNs, as follows:

a) inclusion of INNs with decisions for conditioned inclusion in the List, decisions issued by the President of the NAMMDR, for which cost-volume/cost-volume-result contracts have been concluded, under the terms of Government Emergency Ordinance No. 77/2011 on the establishment of contributions for the financing of health expenditures, approved through Law 184/2015, as further amended and supplemented, and of Order of the Minister of Health and of the President of the National Health Insurance House No. 735/976/2018 on the contract model, negotiation methodology, conclusion, and monitoring of the manner of implementation and performance of cost-volume/cost-volume-result type contracts, as further amended and supplemented;

b) exclusion of the specific annotation of cost-volume (Ω) or cost-volume-result (β) contracts for existing INNs in the List, for which there is an ongoing cost-volume/cost-volume-result contract, which have lost data exclusivity and for their generic(s), respectively their biosimilar(s) which fulfil(s) the conditions of marketing in Romania and for which decision(s) for unconditioned inclusion in the List has/have been issued by the president of the NAMMDR;

c) inclusion of INNs with decisions for unconditioned inclusion in the List, issued by the president of the NAMMDR, for which, on the date of drafting the Government decision to supplement the List, therapy costs per patient/year are lower than those of the comparator which was used in the assessment report issued by the NAMMDR, on the basis of which the decision was issued;

d) inclusion of INNs with decisions for unconditioned inclusion in the List, issued by the president of the NAMMDR, with the designation of orphan medicinal products or advanced therapy medicinal products, for which the

MAH provides evidence, based on the donation notice issued by the NAMMDR, that they have provided treatment for a period of at least 18 months, for at least 50% of the eligible population corresponding to the assessed indication;

e) modification of the annotation with (*), (**) and (**[1]) for INNs in the list;

f) exclusion of INNs with decisions for exclusion from the List, issued by the NAMMDR president.

(2)Within 30 days from the end of each quarter of the year, upon proposal of the NAMMDR, the Ministry of Health prepares the draft decision of the Government for the modification and/or supplementation, as the case may be, of 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, for INNs mentioned in paragraph (1), and forwards it to the Government for approval.

(3) The list is updated once a year for INNs for which the NAMMDR has issued decisions for unconditioned inclusion, other than those provided for in paragraph (1). Within 60 days from the date of publication of the state budget law in the Official Gazette of Romania, Part I, upon proposal of the NAMMDR, the Ministry of Health prepares the draft decision of the Government for the amendment and/or supplementation, as the case may be, of the List and forwards it to the Government for approval.

**Art. 8 -** (1) The NAMMDR can initiate, ex officio, the health technologies assessment procedure for:

1. exclusion of medicinal products from the List in the following cases:

a) INNs corresponding to medicinal products which present changes in terms of safety;

b) INNs corresponding to medicinal products which have changed their status upon release, from medicinal products released only on the basis of a medical prescription to over-the counter medicinal products;

c) INNs corresponding to medicinal products whose marketing authorisation has been withdrawn;

2. the inclusion of INNs corresponding to medicinal products with a valid marketing authorisation in Romania, which are not found in the List.

(2) In the case provided for in paragraph (1), the NAMMDR requests through a notice that the marketing authorisation holder (DMAH) submits the documentation provided in Annex 3, within maximum 30 days from receipt of the notice. If the documentation submitted by the MAH is not complete, the NAMMDR requests the MAH to transmit the missing information within maximum 10 days from receipt of the documentation.

(3) In case of non-compliance with the deadline of maximum 30 days for

submission of the documentation mentioned in Annex 3 or if the MAH does not submit the complete documentation within maximum 10 days after receiving the NAMMDR request, or if the MAH does not agree with the performance of the assessment procedure, the NAMMDR orders the termination of the assessment procedure.

**Art. 8[1]*)** - The NAMMDR shall initiate the assessment procedure of reimbursed INNs in the List in order to move/exclude or mark/eliminate the mark with (*), (**) (**[1]), for those medicinal products for which the specialised commissions within the Ministry of Health or the National Health Insurance House have notified 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 which do not have a therapeutic protocol, respecting the indications, doses and contraindications in the SmPC, within the competence of the prescriber.

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*) Art. 8[1] was introduced by Order of the Minister of Health no. 1.353/2020 of 31 July 2020.

**Art. 9 -** For 2014, reassessment of medicinal products for the List, under the conditions stipulated in this Order, is performed until 30 October 2014.

**Art. 10 -** The National Agency for Medicines and Medical Devices of Romania, 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.

**Art. 11 -** Annexes 1 – 6 are integral parts of this Order.

**Art. 12 -** This Order is to be published in the Official Gazette of Romania, Part I.

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This Order transposes issues related to establishment of the lists of medicinal products for human use 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**

**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

**Art. 1** - In line with this Annex, the following terms shall have the following meaning:

a) **TB** – therapeutic benefit (French: Service Médical Rendu); criteria employed by the institution conducting health technologies assessment in France (Haute Autorité de Santé - 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 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;

d) *** Repealed through Order of the Minister of Health no. 387/2015

e) **INN** - international non-proprietary name recommended by the World Health Organisation (WHO);

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) **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 (*), (**) or (**)[1] 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** – inclusion 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 of Romania;

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

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;

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

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

p[1]) **the line of treatment** represents a particular treatment regimen, with either a single INN, or a combination of INNs, involving a varying number of cycles and a varying duration. Treatment initiation is performed with the first line of treatment, and subsequent lines of treatment (second, third and so on) 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 Autorité de Santé, the French institution performing health technologies assessment;

t)**IQWIG** - Institut fur Qualitat und Wirtschaftlichkeit 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.

aa) **INN with orphan designation** - INN approved by the European Medicines

Agency with orphan designation, used to treat, prevent or diagnose life-threatening or very serious conditions that are rare and affect not more than 5 in 10,000 persons in the European Union. In addition, no satisfactory method for diagnosis, prevention or treatment of such conditions is authorised in the EU or, if such method exists, the respective medicine is a significant benefit to those affected;

ab) **rare diseases INN** - INN whose orphan designation has been withdrawn by the European Medicines Agency or INNs with no former orphan designation, used to treat, prevent or diagnose life-threatening or very serious conditions that are rare and affect not more than 5 in 10,000 persons in the European Union. In addition, no satisfactory method for diagnosis, prevention or treatment of such conditions is authorised in the EU or, if such method exists, the respective medicine is a significant benefit to those affected.

ac) **advanced therapy INN** – 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.

**Art. 2** - Inclusion, extension, non-inclusion, exclusion of medicinal products, addition/relocation of a reimbursed INN in/from the List are performed as per provisions of this Annex, by Decision of the National Agency for Medicines and Medical Devices of Romania, as approved by the specialised NAMMDR structure responsible for health technologies assessment.

**Art. 3** - The National Agency for Medicines and Medical Devices of Romania requires elaboration of therapeutic protocols from Special Commissions of the Ministry of Health, in line with the decision for relocation, inclusion, exclusion or removal/inclusion of the (*), (**) or (**)[1] marking for reimbursable INNs included in the List.

**Art. 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 of Romania.

**Art. 5** - Assessment criteria specified in Table 4 apply to:

a) New INNs;

b) Reimbursable INN with new indication;

c) And d) *** Repealed through Order of the Minister of Health no. 1.353/2020

e) Fixed dose combinations.

**Art. 6** - The evaluation criteria provided in Table 4[1] 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 conditioned inclusion, with ongoing cost-volume/cost-volume-result contracts, which have cumulatively lost data exclusivity and their generic / generics meet/meets the marketing conditions on the Romanian territory;

b) medicinal products corresponding to already reimbursed INNs with decisions for conditioned inclusion, with ongoing cost-volume/cost-volume-result contracts, which have cumulatively lost data exclusivity and whose biosimilar(s) meet the requirements on the Romanian territory.

Table 1 - Criteria for inclusion 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 inclusion 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 inclusion 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. "

*Table 2 - Criteria for ranking reimbursed INNs as (*), (**) or (**)[1]*

| No. | Criteria | Details |
|---|---|---|
| 1. | *** *Repealed through Order of the Minister of Health no. 1.142/2025 of 6 October 2025.* | |
| 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 physician appointed 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.<br>(**)[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 the 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, or approved by the Ministry of Health, according to the internal price notice with the approved value, issued by the Ministry of Health on the date of the assessment, 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

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, without 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 | 30 | | |

| | | | |
|---|---|---|---|
| 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 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 | | |

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, compared with the SmPC, also following a NICE class assessment or assessment of other types of reports/reviews performed by | 15 | Not to exceed 15 points. | |

| | | | |
|---|---|---|---|
| the NHS and related documentation | | | |
| 2.2. New INNs, reimbursable INNs with extension of indication, which have received a positive opinion, 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 | 7 | | |
| 2.3. New INNs, reimbursable INNs with extension of indication, which 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 comparator or for which no evaluation report has been issued | 0 | | |
| 3. Status of INN reimbursement in EU Member States and Great Britain/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 fewer 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:<br>(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;<br>(ii) A EUnetHTA assessment for the submitted indication;<br>(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 | 30 | Not to exceed 30 points | |

| | | | |
|---|---|---|---|
| calculation | | | |
| 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 new INNs, reimbursable INN with extension of indication 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.

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 in relation with 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 nonquantifiable).

4. The phrase "with restrictions in relation with 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 the VAT, 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 14 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 noninterventional study for collection of actual data will be conducted after inclusion of the medicinal product included in the study in the reimbursement system. "

#) In line with Order no. 1.353/2020, the phrase "Department for Health Technologies Assessment" was replaced with the phrase "specialised structure with responsibilities in medical technologies assessment".

Table 4[1] - 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 | 0 | | |

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|---|---|---|---|
| in Great Britain | | | |
| 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 in the List reimbursed in at least 14 of the EU Member States and Great Britain | 25 | Not to exceed 25 points. | |
| 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 in relation with 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 in relation with 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.

*) 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 4[1], 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.

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 |

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|---|---|
| 2. The applicant shall provide one of the following documents for the orphan medicinal product or the advanced therapy medicinal product:<br>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;<br>b) A EUnetHTA assessment for the submitted indication;<br>c) An authorisation for use in last resort treatments in Romania for the medicinal product assessed for the submitted indication;<br>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.

Table 5[1] - 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 |

Table 6 - Criteria for assessment of new, curative INNs for infectious, transmissible diseases with major impact on public health, as included in the national public health programmes of the Ministry of Health

| Criterion | Points |
|---|---|
| 1. New, curative INNs for infectious, transmissible diseases with major impact on public health, as included in the national public health programmes of the Ministry of Health | 55 |
| Number of Member States where the product is reimbursed | |
| 0 - 2 states | 0 |
| 3 - 7 states | 10 |
| 8 - 13 states | 20 |
| 14 - 27 states | 25 |
| 2. Curative INNs for patients with TB, multiple drug-resistant TB: MDR - resistant to at least isoniazid and rifampicin or XDR - resistant to isoniazid, rifampicin, fluoroquinolones and second line injections, as per the WHO guideline on tuberculosis | 80 |

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 the 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 the 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 received the classification BT 3 - insufficient according to the HAS | 0 | | |
| 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 | 7 | | |

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|---|---|---|---|
| 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 | | | |
| 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) 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. | |

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|---|---|---|---|
| 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 INN is the only therapeutic alternative reimbursed in 8 - 13 member states of the EU and Great Britain | 20 | | |
| 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 | 0 | | |

| | | | |
|---|---|---|---|
| member states of the EU and Great Britain | | | |
| 3.5. New INNs, reimbursable INNs with extension of indication, for which the applicant submits at least one of the following documents:<br>(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;<br>(ii) A EUnetHTA assessment for the submitted indication;<br>(iii) Proof of notification to the NAMMDR of a noninterventional 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:<br>a) increases the average survival by at least 3 months; or<br>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 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 | 10 | | |

*) 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 in relation with 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 in relation with 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 specialised 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.

Table 8 - Criteria for assessment of new INNs for the treatment of rare diseases for which the INN is the only therapeutic alternative

| Criterion | Points |
|---|---|
| Criteria for assessment of new INNs for the treatment of rare diseases for which the INN is the only therapeutic alternative | 80 |

Table 9 - Assessment criteria for medicinal products corresponding to a reimbursed INN in the List, with a decision for conditioned inclusion, with an ongoing cost-volume / cost-volume-result contract, which have cumulatively lost data exclusivity and its generic(s), namely whose biosimilar(s) meet(s) 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 conditioned inclusion, biosimilars who have a reimbursed INN in the List, with decisions for conditioned 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 conditioned inclusion, biosimilars who have a reimbursed INN in the List, with decisions for conditioned 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 conditioned inclusion in the List, based on which a cost-volume / cost-volume-result contract was concluded | | |

NOTE:

**** Repealed through Order of the Minister of Health no. 1.142/2025 of 6 October 2025.*

**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, 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, of medicinal products corresponding to new INNs, as well as on extension of indications of medicinal products corresponding to reimbursable INNs

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.

**1.** The applicant submits to the headquarters of the National Agency for Medicines and Medical Devices of Romania, to the attention of the specialised structure with responsibilities in health technologies assessment, an application drawn up according to the template provided in Annex 4 to this Order, both in electronic format and on paper.

**2.** The application must be accompanied by the extensive documentation provided in Annex 3 to this Order, both in electronic format, on CD or DVD, and on paper.

**2[1].**[*)] *For an INN included in the List, with a conditional decision for inclusion, for which there is an ongoing cost-volume/cost-volume-result contract, whose reference medicinal product has lost its data exclusivity and its generic(s), respectively its biosimilar(s) meet(s) the conditions for marketing on the territory of Romania, the NAMMDR initiates the assessment process after receiving the application, drawn up according to the template provided in Annex 4 to this Order, by a marketing authorisation holder for a generic/biosimilar medicinal product.*

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*) Point 2[1] was introduced through Order no. 1.353/2020 of 31 July 2020.

**3.** The application receives a registration number at the National Agency for Medicines and Medical Devices of Romania and the medicinal product enters the assessment procedure, with the decision being communicated to the applicant within maximum 90 working days from receipt of the complete documentation supporting the application.

**4.** If the medicinal product for which the assessment is requested does not have an approved price at the date of submission of the application, the deadline provided for in Point 3 shall be extended by a further 90 days. The applicant shall provide the National Agency for Medicines and Medical Devices of Romania with the appropriate information. If the information supporting the application is not appropriate, the deadline shall be suspended and the National Agency for Medicines and Medical Devices of Romania shall immediately inform the applicant of the additional detailed information required.

**5.** The specialised structure with responsibilities in health technologies assessment within the National Agency for Medicines and Medical Devices of Romania sends confirmation of receipt of the application and the extended documentation which was submitted by the applicant, within maximum 5 working days from their submission.

**6.** Confirmation of receipt of the documents submitted by applicants is made by the specialised structure with responsibilities in health technologies assessment within the National Agency for Medicines and Medical Devices of Romania, by letter with acknowledgement of receipt and by electronic mail (e-mail), with a request for confirmation of receipt and reading from the recipient.

**7.** The preliminary analysis of the assessment reports of the health 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.

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*) In line with Order no. 1.353/2020, the phrase "calendar" has been replaced with the phrase "working".

**8.** After completion of the analysis of medical technology assessment reports, the evidence of reimbursement from European Union Member States and the cost of the therapy, within a maximum of 30 working days from the submission of the documentation, the specialised structure with responsibilities in medical technologies assessment within the National Agency for Medicines and Medical Devices of Romania sends the applicant a confirmation regarding the complete documentation or, as the case may be, informing the applicant about the

required additional information and/or documents, as well as setting up technical meetings with representatives of marketing authorisation holders, if applicable.

**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 supplementation of the submitted documentation, as the case may be.

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*) In line with Order no. 1.353/2020, the phrase "calendar" has been replaced with the phrase "working".

**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.

**11.** To substantiate choice of the comparator relevant for healthcare practice in Romania, the National Agency for Medicines and Medical Devices of Romania requires approval of consulting commissions of the Ministry of Health, within maximum 10 working 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 of Romania the approval concerning choice of a comparator relevant for medical practice in Romania no later than 10 working days as of NAMMDR 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 the NAMMDR decision is delayed by the time calculated from suspension until submission of the additional documentation required.

**15.** If additional documentation is not required, within maximum 90 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, which acquire however elements resulting in possible increase of the initially assigned rating, the Marketing Authorisation Holder or their legal representative may submit a new application accompanied by the extended documentation, but not more than once during the same calendar year.

**17.** If new issues arise, during the assessment period, related to the criteria stipulated in this methodology, which may lead to an increased rating by health technologies assessment, 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.** Received extended applications and documentation are reviewed according to priority, according to the following prioritisation 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 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 applications for assessment have been submitted.

**19.** Requests submitted for inclusion in the List of medicines corresponding to new INNs and for extension of the indications of a medicinal product corresponding to a reimbursed INN, including the change of the current reimbursement status, are posted on the website of the National Agency for Medicines and Medical Devices of Romania, in the section reserved for health technologies assessment, in the order of their registration.

**20.** The following data is included in the table of submitted requests:

a) INN;

b) Trade name;

c) indication;

d) date of submission of request;

e) the date when the National Agency for Medicines and Medical Devices of Romania sends the reply to the applicant.

**21.** The score established for each criterion provided for in Annex 1 to the Order shall be awarded only if the submitted documentation is complete.

**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 their 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. 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 health 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."

**24.** In order to exercise its powers in the field of medical technologies assessment, the National Agency for Medicines and Medical Devices of Romania may request opinions and information from the specialised committees

of the Ministry of Health, the specialised departments of the Ministry of Health, the National Health Insurance House and any institutions subordinated or coordinated by the Ministry of Health.

**24[1].**[*)] 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.

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*) Point 24[1] was introduced through Order no. 1.353/2020 of 31 July 2020.

**25.** The final assessment report is posted on the website of the National Agency for Medicines and Medical Devices of Romania, 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 100 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 of Romania 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 conditioned 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 the health technologies assessment performed in line with this methodology.

**4.** Criteria for decision for exclusion from the List: rating higher than - equal to 50 points by health technologies assessment performed in line with this

methodology.

**5.** Criteria for decision for maintenance in the List:

a) Obtaining a rating lower than 25 points by health technologies assessment performed in line with this methodology leads to maintenance of the INN at the same reimbursement level;

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) of Annex 1 to the Order.

**6.** Criteria for 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 medical technologies assessment;

b) a medicinal product corresponding to an already reimbursed INN which, according to the SmPC, can also be administered in other lines of treatment for the indication for which it was included in the List, based on the medical technologies assessment;

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

**7.** *Criteria for decision for elimination/addition of the (*), (**), or (**[1]) 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) signing cost-volume and cost-volume-result contracts to facilitate patients' ready access to treatment alternatives (establishing the target-patient profile, maximum number of patients treatable and duration of treatment).

**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, 4[1] or Table 7 of Annex 1 to the Order, is administered in two or more treatment regimens or in two or more lines of treatment on the same indication and the same population segment / subgroup, the decision of unconditioned inclusion is issued only if the rating required for unconditioned admission to the List is obtained, for all treatment

regimens / lines. In the other cases, a decision for conditioned inclusion 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 procedure for "addition".

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*) Point 8 was introduced through Order no. 1.353/2020 of 31 July 2020.

**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 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 conditioned inclusion in the List is issued even if the rating obtained after assessment would allow unconditioned inclusion in the List.

———————

*) Point 9 was introduced through Order no. 1.353/2020 of 31 July 2020.

## 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 of Romania 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.** Any decision of the National Agency for Medicines and Medical Devices of Romania to exclude a medicinal product from the List shall contain a justification, based on objective and verifiable criteria. These decisions, including, where appropriate, any opinion or recommendation of the specialised committees of the Ministry of Health on which the decisions are based, shall be communicated to the applicant within maximum 7 working days from their issuance, and the applicant shall also be informed of the available means of appeal, in line with the legislation in force, and of the deadlines for exercising them.

**3.** If the marketing authorisation holder does not agree with the issued decision, they may file an appeal with the National Agency for Medicines and Medical Devices of Romania, within 7 working days from receipt of the official communication sent by the national competent authority.

**$3^1$.***) If the court orders by executory decision the obligation of the NAMMDR to solve a request made by a petitioner to include a medicinal product in the List, the NAMMDR shall proceed with priority to analysing the application and shall 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.

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*) Point $3^1$ was introduced through Order no. 1.353/2020 of 31 July 2020.

**4.** The Commission for resolution of complaints is approved through Order of the Minister of Health and is composed of: a representative of the Ministry of Health, 2 representatives of the National Agency for Medicines and Medical Devices of Romania and 2 representatives of the National Health Insurance

House.

The representatives of the National Agency for Medicines and Medical Devices of Romania nominated in the appeals resolution committee will be other persons than those included in the specialised structure with responsibilities in health technologies assessment and involved in the assessment process.

Representatives of the marketing authorisation holder who filed the appeal, of the associations of medicinal product manufacturers and of patient associations, who are observers, without the right to vote, may participate in the meetings of the appeals resolution committee.

**5.** The Appeals Resolution Committee will assemble no later than 30 days after the appeals are submitted.

The National Agency for Medicines and Medical Devices of Romania shall communicate to the marketing authorisation holder who has filed an appeal or to their legal representative in Romania, in writing, the date set for the meeting of the appeals resolution committee, at least two working days before the date on which it is scheduled.

**6.** The decisions of the appeals resolution committee are taken by open vote, by simple majority voting and are recorded in the minutes of the meeting.

**7.** The minutes of the meeting and the decision of the appeals resolution committee are officially communicated to the applicant, within maximum 7 working days from the date of the meeting of the appeals resolution committee, and are posted on the website of the National Agency for Medicines and Medical Devices of Romania in the section for health technologies assessment.

**8.** If the marketing authorisation holder or their legal representative does not agree with the decision of the appeals resolution committee, they may further address the competent administrative 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 of Romania 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: statutory declaration of the Marketing Authorisation Holder regarding the countries where the medicinal product is reimbursed for the respective indication;

e) the price approved by the Ministry of Health, copy issued by the CANAMED, or internal price notice with the approved value, issued by the Ministry of Health;

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

g) letter of Marketing Authorisation Holder commitment attesting their 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**

| **1. Medicinal product identification data** |
|---|

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 unit dose: |

**4. Marketing Authorisation Holder**

Company name:
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 27 Member States of the European Union)**

Country:
Reimbursed (yes/no):
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 of Romania 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 and stamp of the applicant; date**

Signature and stamp of the Applicant

.....

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) penalties 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 3 are

assigned through Order of the Minister of Health and of the President of the National Health Insurance House.

**Annex 6**[*)]

*) Annex 6 was introduced through Order no. 387/2015 of 2 April 2015.

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 .....…. 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 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, as further amended and supplemented,

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

1.– Unconditional inclusion;
- Non-inclusion;
- Exclusion;
- Conditional inclusion;
- Addition;
- Relocation;
- Marking of a reimbursable INN with (*), (**), (**)[1];
- Elimination of ranking of a reimbursable

INN as (*), (**) or (**)[1],
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, in the 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 of Romania,**

.....