ORDER no. 861 of 23 July 2014

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

ISSUED: THE MINISTRY OF HEALTH

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

Taking into account provisions of:

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

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

the Minister of Health hereby issues the following Order:

ARTICLE 1

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

ARTICLE 2

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

ARTICLE 3

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

ARTICLE 4

The template for the application to be submitted to the Registry Office of the National Agency for Medicines and Medical Devices concerning assessment of health technologies in

support of the proposal for inclusion into the List of new INNs, reimbursable INNs with extension of indication, generics with non-reimbursable INNs, biosimilars with non-reimbursable INNs and fixed-dose combinations, as mentioned in Annex 4, is hereby approved.

ARTICLE 5

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

ARTICLE 5[1*)]

The template for decision of the National Agency for Medicines and Medical Devices is hereby approved on medicinal product inclusion/non-inclusion into /exclusion from the List, extension of indications, relocation/addition of reimbursed INNs, ranking of reimbursed INNs by (*), (**)1 or (**)2 in/of the List, as provided in Annex 6.

ARTICLE 6

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

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

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

ARTICLE 7

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

ARTICLE 8

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

a) INNs corresponding to medicinal products with safety amendments;

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

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

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

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

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

ARTICLE 10
The National Agency for Medicines and Medical Devices, the Ministry of Health, the special commissions of the Ministry of Health, directorates and institutions subordinated or coordinated by the Ministry of Health, as well as the National Health Insurance House, shall fulfil the provisions of this Order.

ARTICLE 11
Annexes 1 – 6 are integral parts of this Order.

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

*

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

Minister of Health,

Nicolae Bănicioiu

ANNEX 1

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

ARTICLE 1
In line with provisions of this Annex, the following terms shall have the following meaning:
a) **TB** – therapeutic benefit (French: Service Medical Rendu); criteria employed by the institution conducting health technologies assessment in France (Haute Autorite de Sante - HAS), for medicinal product inclusion into/exclusion from the List of International Non-proprietary Names of medicinal products provided to insurants, irrespective of personal contribution, based on medical prescription, in the health insurance system frame, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programmes, hereinafter the List, and establishment of a reimbursement regimen;

there are 3 TB levels: TB 1 - major/important; TB 2 - moderate/low (nonetheless 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, as well as INNs relating to medicinal products provided in the frame of national healthcare programs, approved through Government Decision no. 720/2008, as amended, with the same approved indication, meant for the same population group and with the same pharmacodynamic properties as INNs assessed. INNs included in the List of INNs of on-prescription medicinal products provided to insurants within the healthcare insurance system, irrespective of personal contribution, as well as INNs relating to medicinal products provided in the frame of national healthcare programs, approved through Government Decision no. 720/2008, as amended, included into the list based on cost-volume and cost-volume-outcome contracts may not be considered comparators;
d) *** repealed by Order of the Minister of Health no. 387/2015;
e) **INN** – international non-proprietary name recommended by the World Health Organisation;
f) **reimbursed INN** - international non-proprietary name included in the List;
g) **new INN** - INN not included in the List;
h) **reimbursed 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 (*), (**)1, or (**)2 ranking;
l) **extension of indication** – addition of a new pathology/disease for which the respective INN has demonstrated safety and efficacy, also included in the Summary of Product Characteristics reviewed by the European Medicines Agency or the National Agency for Medicines and Medical Devices (extension of indication does not include the following: change of the age group, new population segment, change of treatment line, relocation/change of treatment line);
m) **relocation** - withdrawal of a reimbursable INN from a sublist/ List section and its inclusion into a different sublist/ List section;
n) **addition** – inclusion of a reimbursable INN in a different sublist/ List section as well, in addition to the previous one;
o) **exclusion** – withdrawal of reimbursable status of a reimbursable INN within the List;
p) **removal/addition of the (*), (**)[1], or (**)[2] ranking** – change of conditions for prescriptions of treatment with medicinal products corresponding to reimbursable International Non-proprietary Names included in the List;
p1) **treatment line** - therapeutic schedule conducted with a single INN/an INN combination, consisting of a varied number of cycles and of varied duration. Therapy is started with the first line treatment, whereas subsequent treatment lines (second, third and so on) may be initiated at any time disease progression becomes documented;
q) **cycle of treatment** – period including administration of an INN (possibly performed over one or several successive or different days) and the free-of-treatment period to next administration;
r) **HTA** - health technologies assessment;
s) **HAS** - Haute Autorite de Sante, the French institution performing health technologies assessment;

t) **IQWIG** - Institut für Qualität und Wirtschäftlichkeit im Gesundheitswesen, German institution performing health technologies assessment;
u) **G-BA**: der Gemeinsame Bundesausschuss (G-BA), German institution performing health technologies assessment;
v) **NICE** - National Institute of Health and Care Excellence, the institution performing health technologies assessment in England, Northern Ireland and Wales;
w) **GDP** – Gross Domestic Product, expressed in LEI and published by the National Institute of Statistics;
x) **SmPC** - Summary of Product Characteristics;
y) **Scottish Medicines Consortium (SMC)** - the institution performing health technologies assessment in Scotland.
aa) **orphan INN** – 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.

ARTICLE 2
Inclusion/non-inclusion into/exclusion from, relocation in the List, extension of indication, removal/addition of a reimbursed INN, assignment of the (*), (**)1, or (**)2 ranking to a reimbursed INN in the List are only performed in compliance with provisions of this Annex, by Decision of the National Agency for Medicines and Medical Devices, based on the report of the specialised NAMMD unit responsible for health technologies.

ARTICLE 3
The National Agency for Medicines and Medical Devices requires elaboration of therapeutic protocols from Special Commissions of the Ministry of Health, in line with the decision for relocation, addition, exclusion or removal/addition of the (*), (**)1, or (**)2 ranking related to reimbursable INNs included in the List.

ARTICLE 4
Specialised commissions of the Ministry of Health draft therapeutic protocols provided for in Article 3 no later than 30 days as of receipt of the application submitted by the National Agency for Medicines and Medical Devices.

ARTICLE 5
Assessment criteria specified in Table 4 apply to:
a) New INNs;
b) Reimbursable INN with new indication;
c) Generic medicinal products whose INNs are not reimbursable according to the List;
d) Biosimilars whose INNs are not reimbursable according to the List;
e) Fixed dose combinations.

Table 1 - Criteria for addition/relocation of reimbursed INNs

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

NOTE:

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

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

No.	Criteria	Details
1.	High cost INNs(i) prescribed and dispensed based on therapeutic protocols entered into the Electronic Register of the Health Insurance House of high-cost medicines under monitoring (**)[2]	Treatment with medicinal products corresponding to INNs ranked (**)[2] is conducted based on therapeutic protocols established by specialised commissions of the Ministry of Health, subject to monitoring through the Register of the Health Insurance House of high-cost medicines and/or started in non-interventional studies carried out in Romania, for collection of real-life data for HTA purposes
2.	Medium-cost INNs(i) prescribed and dispensed by the assigned doctor based on therapeutic protocols only (**)[1]	Treatment with medicinal products corresponding to INNs ranked (**)[1] is conducted based on therapeutic protocols established by specialised commissions of the Ministry of Health
3.	Low-cost INNs (ii) requiring medical prescription according to SmPC	*Treatment with medicinal products corresponding to INNs ranked (*) is started by specialist doctors within their respective competence and may further be prescribed by general practitioners based on a medical letter issued by the specialist doctor.

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

[*] Monthly treatment cost - total price of the INN calculated at the maximum retail price level with VAT, included in the National Catalogue of prices of medicinal products for human use approved on assessment date, according to doses and administration duration as provided in the SmPC, for one calendar month. The monthly treatment cost is calculated for each strength, pharmaceutical form or route of administration of the respective INN. The (*), (**)1 or (**)2 ranking of reimbursed INNs depends on the pharmaceutical form with the highest monthly treatment cost.

(ii) Products whose calculated monthly treatment cost** is < minimum gross wages on the date of the decision for inclusion into the List

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 25 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	25		
2. Cost-efficacy based HTA - Great Britain (NICE/SMC)			
2.1. INN approved, with no restrictions, by the Great Britain health technologies assessment authority.	0	Not to exceed 25 points.	
2.2. INN not assessed by the Great Britain authority for assessment of health technologies (NICE/SMC).	10		
2.3. INN approved upon review, with restrictions in relation with the SmPC, by the Great Britain authority for assessment of health technologies (NICE/SMC)	15		
2.4. INN not approved for inclusion in the reimbursement system by the Great Britain authority for assessment of health technologies (NICE/SMC)/for which approval for inclusion in the system has been withdrawn/included in the negative list of the Great Brittan National Healthcare Service	25		

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, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, classified as BT1-major/important by the HAS	15	Not to exceed 15 points.	
1.2. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List,			

** GDP Reference: the National Institute of Statistics, the latest published Statistical Yearbook of Romania

classified as BT2-moderate/low (nonetheless justifying reimbursement) by the HAS.7			
2. HTA based on cost-efficacy			
2.1. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, approved without restrictions in relation with the SmPC by Great Britain authorities for assessment of health technologies (NICE/SMC 15 Not to exceed 15 points.			
2.2. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, approved with restrictions in relation with the SmPC by Great Britain authorities for assessment of health technologies 7			
2.3. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INNs in the List approved without restrictions in relation with the SmPC by German authorities for assessment of health technologies (IQWIG/G-BA)	15	Not to exceed 15 points.	
2.4. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INNs in the List, approved with restrictions in relation with the SmPC by German authorities for assessment of health technologies (IQWIG/G-BA)	7		
3. Status of INN reimbursement in Member States/Positive assessment report from the National Agency for Medicines and Medical Devices			
3.1. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INNs in the List, for which inclusion into the List of the new therapeutic indication is required, reimbursed in at least 14 Member States	25	Not to exceed points.	
3.2. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INNs in the List, reimbursed in 8-13 Member States	20		
3.3. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INNs in the List, reimbursed in 3-7 Member States	10		
3.4. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INNs in the List, reimbursed in less than 3 Member States	0		

3.5. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INNs in the List or fixed-dose combinations of already reimbursable INNs, authorised for marketing, for which the MAH has collected real-life data from clinical trials initiated and conducted in Romania for HTA purposes, whose protocol and endpoints have been approved by the National Agency for Medicines and Medical Devices	45	Not to exceed 45 points	
4. Therapy costs			
4.1. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INNs in the List, generating 5% savings more than the comparator for the medicinal product budget of the assessment year	30	Not to exceed 30 points.	
4.2. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INNs in the List, with neutral budget impact in relation with the comparator (+/-5%) of the medicinal product budget in the assessment year	15		
4.3. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INNs in the List, generating costs at least 5% higher than the comparator for the medicinal product budget of the of assessment year	0		

NOTE:

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

For applicants seeking to initiate and conduct in Romania a non-interventional study for collection of real -life data for HTA purpose, the 45 points awarded as per 3.5 shall replace the score granted for reports HTA authorities in France (HAS), UK (NICE/SMC) and Germany (IQWIG/G-BA) described under 1 and 2 of the table.

Given the lack of consistency among non-interventional studies on pathologies, patient population, endpoints pursued, type of data collected, analysis and interpretation of results, a single methodology for all types of non-interventional studies is almost impossible to develop. Protocols submitted by the applicants are to reviewed by the Medical Technology Assessment

[*] Cost/Recommended Daily Dose (annual RDD) - INN total price calculated at the maximum retail price with VAT, as provided in the in the National Catalogue of Prices of Medicinal Products for Human Use approved on the date of assessment, depending on the doses and the duration of administration provided in the SmPC for one calendar year. The cost/Recommended Daily Dose (annual RDD) is calculated for the same strength, pharmaceutical form or route of administration of the INN, and, in case both the innovative drug and the generics for the fixed combination components are marketed, the annual costs/annual RDD of the components taken separately are summated at the level of the generics with the lowest retail prices with VAT specified in the National Catalogue of Prices of Medicinal Products for Human Use approved on assessment date.

Department and the Clinical Trials Service within the National Agency for Medicines and Medical Devices. The National Agency for Medicines and Medical Devices may consult with representatives of the National Health Insurance House and the advisory committees of the Ministry of Health. Respective endpoints are assessment of the additional clinical benefit, safety, quality of life issues and the collection of direct costs from the payer's perspective to carry out pharmacoeconomic analyses at the end of the study.
The purpose of the working group is to examine the design of the non-interventional study and guide the applicant to a protocol for collecting real-life data from the therapeutic practice for HTA purposes. Such non-interventional studies shall comply with regulations stipulated in the Decision of the Scientific Council of the National Agency for Medicines and Medical Devices no. 6/2014 on authorisation by the National Agency of Medicines and Medical Devices/notification to the National Agency of Medicines and Medical Devices of non-interventional studies performed with medicinal products for human use in Romania, as amended by Decision of the Scientific Council of the National Agency of Medicine and Medical Devices no. 25/2015.

Table 5 – Criteria for assessment of new INNs authorised as orphan drugs by the European Medicines Agency

Criteria	**Rating**
Treatment, prevention or diagnosis of 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	55
Number of Member States where the product is reimbursed (out of 27)	
0 - 2 states	0
3 - 7 states	10
8 - 13 states	20
14 - 27 states	25

NOTE:
The criteria for the decision to include, extend the indications of or non-inclusion into the List of medicines approved as orphan drugs by the European Medicines Agency are the same as set out in Annex no. 2, I, B, 1) and 2) to this Order.

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

Criteria	**Rating**
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

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, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for the treatment of rare diseases/advanced stages of pathologies for which the INN is the only therapeutic alternative, BT 1 - major/important according to HAS classification	15	Not to exceed 15 points.	
1.2. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for the treatment of rare diseases/advanced stages of pathologies for which the INN is the only therapeutic alternative, BT 2 - moderate/low (nonetheless justifying reimbursement) according to HAS classification	7		
2. HTA based on cost-efficacy			
2.1. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for the treatment of rare diseases/advanced stages of pathologies for which the INN is the only therapeutic alternative approved without restrictions in relation with the SmPC by Great Britain authorities for assessment of health technologies (NICE/SMC)	15	Not to exceed 15 points.	
2.2. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for the treatment of rare diseases/advanced stages of pathologies for which the INN is the only therapeutic alternative approved with restrictions in relation with the SmPC by Great Britain authorities for assessment of health technologies (NICE/SMC)	7		
2.3. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for the treatment of rare diseases/advanced stages of pathologies for which the INN is the only therapeutic alternative for which the report prepared by the German authorities for assessment of health technologies (IQWIG/G-BA) demonstrates additional therapeutic benefit in relation with the comparator	15	Not to exceed 15 points.	
2.4. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for the	7		

treatment of rare diseases/advanced stages of pathologies for which the INN is the only therapeutic alternative for which the report prepared by the German authorities for assessment of health technologies (IQWIG/G-BA) demonstrates no additional therapeutic benefit in relation with the comparator			
3. Status of INN reimbursement in Member States/Positive assessment report from the National Agency for Medicines and Medical Devices			
3.1. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for the treatment of rare diseases/advanced stages of pathologies for which the INN is the only therapeutic alternative, reimbursed in at least 14 Member States	25	Not to exceed 25 points.	
3.2. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for the treatment of rare diseases/advanced stages of pathologies for which the INN is the only therapeutic alternative, reimbursed in 8 - 13 Member States	20		
3.3. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for the treatment of rare diseases/advanced stages of pathologies for which the INN is the only therapeutic alternative, reimbursed in 3 - 7 Member States	10		
3.4. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for the treatment of rare diseases/advanced stages of pathologies for which the INN is the only therapeutic alternative, reimbursed in fewer than 3 Member States	0		
3.5. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INNs in the List or fixed-dose combinations of already reimbursable INNs, authorised for marketing, for which the MAH has collected real-life data from clinical trials initiated and conducted in Romania for HTA purposes, whose protocol and endpoints have been approved by the National Agency for Medicines and Medical Devices[*]	45	Not to exceed 45 points.	

[*] For applicants seeking to initiate and conduct in Romania a non-interventional study for collection of real -life data for HTA purpose, the 45 points awarded as per 3.5 shall replace the score granted for reports HTA authorities in France (HAS), UK (NICE/SMC) and Germany (IQWIG/G-BA) described under 1 and 2 of the table.
Given the lack of consistency among non-interventional studies on pathologies, patient population, endpoints pursued, type of data collected, analysis and interpretation of results, a single methodology for all types of non-interventional studies is almost impossible to develop. Protocols submitted by the applicants are to reviewed by the Medical Technology Assessment Department and the Clinical Trials Service within the National Agency for Medicines and Medical Devices. The National Agency for Medicines and Medical Devices may consult with representatives of the National Health Insurance House and the advisory committees of the Ministry of Health.

3. Stage of the disease			
4.1. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for the treatment of rare diseases/advanced stages of pathologies for which the INN is the only therapeutic alternative in patients whose average estimated survival is under 12 months	10	Not to exceed 30 points.	
4.2. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for the treatment of rare diseases/advanced stages of pathologies for which the INN is the only therapeutic alternative, for which the treatment increases average the estimated survival by at least 3 months	10		
4.3. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for treatment of diseases life-threatening or very serious conditions that are rare and affect not more than 5 in 10,000 persons in the European Union, are chronically debilitating or constitute serious and chronic diseases.	10		

NOTE:

The criteria for the decision to include, extend the indications of or non-inclusion into the List of medicines approved by the European Medicines Agency as orphan drugs, products for the treatment of rare diseases or advanced stages of diseases for which the INN is the only therapeutic alternative are the same as set out in Annex no. 2, I, B, 1) and 2) to this Order.

Table 8 – Criteria for assessment of new INNs, plasmatic derivatives for the treatment of rare diseases for which the respective INNs are the only therapeutic alternative

Criterion	**Rating**
New INNs, plasmatic derivatives for the treatment of rare diseases for which the respective INNs are the only therapeutic alternative	80

Respective endpoints are assessment of the additional clinical benefit, safety, quality of life issues and the collection of direct costs from the payer's perspective to carry out pharmacoeconomic analyses at the end of the study. The purpose of the working group is to examine the design of the non-interventional study and guide the applicant to a protocol for collecting real-life data from the therapeutic practice for HTA purposes. Such non-interventional studies shall comply with regulations stipulated in the Decision of the Scientific Council of the National Agency for Medicines and Medical Devices no. 6/2014 on authorisation by the National Agency of Medicines and Medical Devices/notification to the National Agency of Medicines and Medical Devices of non-interventional studies performed with medicinal products for human use in Romania, as amended by Decision of the Scientific Council of the National Agency of Medicine and Medical Devices no. 25/2015.

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

ANNEX 3

DOCUMENTATION

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

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

2. In addition to the application specified under point 1, the applicant shall also submit the following documents:
a) health technologies assessment reports issued by authorised agencies in France, Great Britain and Germany;
b) data required for calculation of therapy costs, as shown in Table 1 of Annex 2 to this Order;
c) the Summary of Product Characteristics approved by the National Agency for Medicines and Medical Devices or, as required, for the centralised procedure, by the European Medicines Agency on behalf of the European Commission;
d) proof of reimbursement in Member States: link(s) which attesting the reimbursement status or, if the information is not public, a statutory declaration of the Marketing Authorisation Holder;
e) the price approved by the Ministry of Health (copy issued by the CANAMED, decision for price approval or proof for submission of the price dossier to the competent authority for approval of medicinal product prices);
f) proof of payment of the fee for health technologies assessment by the National Agency for Medicines and Medical Devices, approved in accordance with the law;
g) letter of Marketing Authorisation Holder commitment attesting their firm undertaking to become involved in a cost-volume or cost-volume-outcome mechanism, in case of individually calculated ratings allowing for conditioned inclusion into the List.

ANNEX 4

- Template -

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

1. Medicinal product identification data

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 Member States)

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 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**: ……/……/…….

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-outcome contracts

1. Cost-volume and cost-volume-outcome 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-outcome:
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-outcome contracts are negotiated between the marketing authorisation holder or their legal representative in Romania and representatives of the Ministry of Health and of the National Health Insurance House.
6. Representatives of the Ministry of Health and of the National Health Insurance House signatory of the contracts mentioned under points 2 and are assigned through Order of the Minister of Health and of the President of the National Health Insurance House.

ANNEX 6[*]

THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES

DECISION
no. ….. /…..

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

Taking into account the Assessment report set out by the Department for Health Technologies Assessment of the National Agency for Medicines and Medical Devices pursuant to provisions of Order no 861/ 2014 on approval of criteria and methodology for assessment of health technologies, of documentation to be submitted by applicants, methodological means used in the assessment for inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs, as well as the means for appeal thereof, as amended,

based on Article 8 (3) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

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

1. - Unconditional inclusion
   - Non-inclusion
   - Exclusion
   - Conditional inclusion
   - Extension of indications
   - Addition/Relocation of a reimbursable INN
   - Ranking of a reimbursable INN as (*), (**)[1] or (**)[2]

   of the INN:…….

[*] Annex 6 has been introduced as of 2 April 2015, by Order of the Minister of Health no. 387/2015

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

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

……