Having regard to the Prime Minister's Decrees of July 11, 2019, January 9, 2020, and October 21, 2020;

Having regard to Memorandum No. 3817 of January 10, 2024 of the Molise Re- gion, in which, among other things, account was given of the verification carried out on BDAP of the fi- nancial, physical and procedural monitoring data and the payment schedule, limited to public works, deduced from the system referred to in Legislative Decree No. 229 of December 29, 2011;

Considered, therefore, necessary, to adopt an ordinance pursuant to Article 1, paragraph *4-undevicies,* of Decree-Law No. 125 of October 7, 2020, converted, with amendments.
cations, by Law No. 159 of Nov. 27, 2020, by which to seamlessly enable the prose- cution of the interventions financed with the resources referred to in Article 1, paragraphs 1028 and 1029, of Law Dec. 30
2018, n. 145;

By agreement with the Molise Region;

In consultation with the Ministry of Economy and Finance;

Features:

Art. 1.

Extension of the validity of special account No. 6067

1. In order to allow without solution of continuity the completion of the interventions financed with the resources allocated pursuant to Article 1, paragraphs 1028 and 1029, of Law No. 145 of December 30, 2018, or co-financed with them, the vigor of the special account No. 6067, opened pursuant to the Order of the Head of the Department of Civil Protection No. 481 of September 11, 2017, already extended until December 31, 2023 pursuant to the Order of the Head of the Department of Civil Protection
No. 843/2022, is further extended until Dec. 31, 2024.

This ordinance will be published in the *Official Gazette of* the Italian Republic.

Rome, January 24, 2024

The Head of the Department:
CURCIO

24A00589

DECREES AND RESOLUTIONS OF OTHER AUTHORITIES

ITALIAN DRUG AGENCY

DETERMINATION January 29, 2024.

**Inclusion of the drug Setmelanotide (Imcivree) in the list established under Law Dec. 23, 1996,
No. 648, for the treatment of obesity and hunger control associated with hypothalamic acquired obesity (HO) from craniopharyngioma of patients older than 6 years of age.** (Determination No. 11003).

THE DIRECTOR.
OF THE PRE-CLEARANCE AREA

Having regard to Articles 8 and 9 of Legislative Decree No. 300 of July 30, 1999;

Given Article 48 of the Decree-Law of September 30, 2003,
No. 269, converted with amendments by Law No. 326 of Nov. 24, 2003, establishing the Italian Medicines Agency (AIFA);

Having regard to the Decree of the Minister of Health, in concer- dence with the Minister of the Civil Service and the Minister of Economy and Finance, September 20, 2004, No. 245, as amended, containing rules on the organization and operation AIFA;

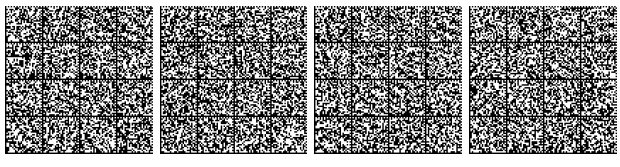
Having regard to the Rules of Organization, Functioning and Personnel Order of AIFA, adopted by the Board of Directors by Resolution No. 12 of April 8, 2016;

Having regard to the decree of the Minister of Health dated January 20, 2023, by which Dr. Anna Rosa Marra, effective January 25, 2023, was appointed as a substitute for the director general of the Italian Drug Agency, pending the implementation of the provisions of Article 3 of Decree-Law No. 169 of 2022, converted, with amendments, by Law No. 196 of 2022."

Given the determination of the deputy director general No. 44 of Feb. 8, 2023, of confirmation of the director general's determination No. 1034 of Sept. 8, 2021, by which Dr. Sandra Petraglia, manager of the pre-authorization area, was delegated to adopt the prov- ions for the authorization of the expenditure of orfa- ni drugs for rare diseases and drugs that represent a hope of cure, pending commercialization, for particular and serious diseases, within the limits of the availability of the "5% Fund," referred to in Art. 48, paragraphs 18 and 19, lettera *(a)*, of Decree-Law No. 269/2003, converted with mo- difications by Law No. 326/2003, and of the measures for updating the list of medicines that can be dispensed a t full charge of the National Health Service, pursuant to Law No. 648/1996;

Having regard to the decree of the Minister of Health September 20, 2018, which reconstituted the AIFA's Technical and Scientific Advisory Commission (STC), referred to in Article 19 of the Decree of the Minister of Health September 20, 2004, No. 245, for a term of three years;

Given Article 38 of the Decree-Law of November 6, 2021,
No. 152, converted into law, with amendments, by Article 1, Paragraph 1, Law No. 233 of December 29, 2021, which provides for



The extension of the Technical and Scientific Advisory Commission and the Pricing and Reimbursement Committee operating at the Italian Drug Agency until Feb. 28, 2022, subsequently extended until Dec. 1, 2023, by virtue of Decree-Law No. 132 of Sept. 29, 2023;

Given Decree-Law No. 536 of October 21, 1996, converted, with amendments, by Law Dec. 23, 1996, No. 648, on measures for the containment of pharmaceutical expenditure and the determination of the expenditure ceiling for the year 1996 and, in particular, Article 1, paragraph 4, which di- sposes the full charge of the National Health Service for innovative medicines whose commercialization is authorized in other states but not in the national territory, medicines not yet authorized but undergoing clinical trials and medicines to be used for a therapeutic indication other than the authorized one;

Having regard to the measure of the Single Commission on Medicines (CUF), dated July 20, 2000, published in the *Official Gaz*ette No. 219 of September 19, 2000 with *errata- corrige* in the *Official Gazette* No. 232 of October 4, 2000, concerning the establishment of the list of ero- gable medicines fully paid for by the National Health Service under Law No. 648 of December 23, 1996;

Having regard to the CUF order of January 31, 2001, con- cerning the clinical and expenditure monitoring of medicines included in the above-mentioned list, published in the *Official Gazette of* March 24, 2001, No. 70;

Consider the evidence for the efficacy and safety of the drug "setmelanotide" (Imcivree) in the treatment of obesity and hunger control associated with hypothalamic acquired obesity (HO) from craniopharyngioma;

Considered it appropriate to allow the prescription of the said medicine at the full cost of the National Health Service for patients with craniopharyngioma over the age of six;

Taking into account the decision made by the STC at its meeting on July 5, 6 and 7, 2023 - excerpt from Minute No. 91;

Having regard to the approval resolution of the AIFA board of directors dated September 20, 2023, No. 30;

Considered, therefore, to include the medicine "setme- lanotide" (Imcivree) in the list of medicines that can be fully paid for by the National Health Service, established in accordance with Law No. 648 of December 23, 1996, for the treatment of obesity and hunger control associated with acquired hypothalamic obesity (HO) by craniopharyngeal- ma of patients older than six years of age;

Determination:

Art. 1.

1. The drug SETMELANOTIDE (Imcivree) is in- seritated, pursuant to Article 1, Paragraph 4, of Decree-Law No. 536 of October 21, 1996, converted by Law No. 648 of December 23, 1996, in the list established by the order of the Single Drug Commission, and is dispensable, at full charge of the National Health Service, for the treatment of obesity and associated hunger control

to acquired hypothalamic obesity (HO) from craniopharyngeal- but of patients older than six years of age, subject to the conditions specified in the annex that is an integral part of this determination.

2. For the purpose of consulting the lists of drugs fully paid for by the National Health Service, riman- da the lists published on AIFA's institutional website www.aifa.gov.it

Art. 2.

This determination shall take effect on the day following its publication in the *Official Gazette of* the Italian Re- public.

Rome, January 29, 2024

The executive:
PETRAGLIA

ANNEX *1*

Name: SETMELANOTIDE (Imcivree).

Therapeutic indication: treatment of obesity and hunger control associated with hypothalamic acquired obesity (HO) from craniopharyngeal- but of patients older than six years.

Inclusion criteria:

Children/adolescents with craniopharyngioma (CP) with age > six years, already obese at diagnosis with persistent obesity after six to twelve months after CP diagnosis and at least one co-morbidity (see list below)*;

Children/adolescents with CP aged > six years, with class III obesity defined as 140% of the 95th percentile at six to 12 months after CP surgery/diagnosis.

All patients should present with hypothalamic involvement rilevated by MRI (grade 1-2).

*List: co-morbidities of obesity:

a. type 2 diabetes;

b. Moderate-severe obstructive sleep apnea syndrome (OSAS) (apnea-hypopnea index-AHI- >15) if class II obesity; mild OSAS (AHI >5) if class III obesity;

c. Nonalcoholic steatohepatitis with significant fibrosis;

d. pseudotumor cerebri;

e. hypertension;

f. dyslipidemia;

g. impaired glucose tolerance.

Exclusion criteria:

Current, clinically significant pulmonary, cardiac, or oncologic disease;

Glomerular filtration rate (GFR) < 30 ml/min/1.^{73m2}; significant

dermatological findings related to skin lesions of Melanoma or pre-melanoma;

History or close family history (parents or siblings) of skin cancer or melanoma;

weight gain >5% in the previous three months;

weight loss ≥2% in the previous three months;

diagnosis of severe psychiatric disorders;

HbA1c>10.0%;

Inability to comply with the once-a-day injection regimen.

Prescription period fully paid by the National Health Service:

Until further determination by the Italian Drug Agency.

Treatment plan

"Setmelanotide" should be administered subcutaneously once daily, early in the day (to maximize hunger reduction during the daytime period when awake), indepen- dently of meals. "Setmelanotide" should be administered subcutaneously in the abdomen, alternating the injection site in the abdominal area each day.

The dose range is 0.25-3.0 mg once daily by subcutaneous injection, depending on the patient's age and any altered kidney and liver function.

Other conditions to be observed:

the procedures provided for in Articles 4, 5, 6 of the measure dated July 20, 2000 cited in the introduction, in relation to: Article 4: establishment of the registry, detection and transmission of clinical monitoring data and information regarding treatment suspensions (by means of special form as per the measure of January 31, 2001, published in the *Official Gazette* No. 70 of March 24, 2001); Article 5: acquisition of informed consent, prescription and dispensing procedures for the drug; Article 6: detection and transmission of expenditure data.

Parameters for clinical monitoring

Skin monitoring

Annually, before and during treatment with "setmelanotide," whole-body dermatological examinations should be performed to mo- nitor pre-existing and new skin pigmentary lesions.

Monitoring of heart rate and blood pressure

For patients being treated with "setmelanotide," it is necessary to mo- nitor heart rate and blood pressure at each medical visit (at least every six months) as part of clinical practice *standards*.

Depression

Patients with depression should be monitored at each medical visit during treatment with "setmelanotide." Discontinuation of "setmelanotide" should be considered if pa- tients manifest suicidal thoughts or behaviors.

Monitoring growth and cognitive development

In growing children, the impact of weight loss on growth and cognitive development should be assessed. Growth (height and weight) should be monitored using age- and sex-appropriate growth curves.

Prolonged penile erection

Patients who present with penile erection lasting longer than four hours should be informed to seek emer- gency services for possible priapism treatment.

Presence of benzyl *alcohol*

Imcivree medication contains 10 mg benzyl *alcohol* per cia- scun mL. Benzyl alcohol may cause allergic reactions.

This medication should be used with caution in patients with hepatic or renal impairment because of the potential risk from the excipient benzyl alcohol, which could accumulate over time and cause metabolic acidosis.

24A00619

DETERMINATION January 29, 2024.

Reimbursement scheme and price, as a result of new therapeutic in- dications, of the medicinal product for human use "Im- civree." (Determination No. 57/2024).

THE DIRECTOR.
OF THE SECTOR HTA AND DRUG ECONOMICS

Given Article 48 of the Decree-Law of September 30, 2003,
No. 269, on "Urgent provisions to promote development and to correct trends in public accounts," converted, with amendments, into Law No. 326 of Nov. 24, 2003, which established the Italian Drug Agency and, in particular, paragraph 33, which provides for price negotiation for products reimbursed by the National Health Service between the Agency and manufacturers;

Having regard to Decree No. 245 of September 20, 2004, of the Ministry of Health, in consultation with the Ministers of the Civil Service and of Economy and Finance, laying down rules on the organization and operation of the Italian Drug Agency, issued pursuant to Article 48, paragraph 13, above, as amended by Decree No. 53 of the Ministry of Health in consultation with the Ministers of Public Administration and Simplification and of Eco- nomy and Finance of March 29, 2012;

Having regard to the Regulations on the Organization, Functioning and Organization of the Personnel of the Italian Medicines Agency, published on the institutional website of the Agency (notice in the *Official Gazette of* the Italian Republic - General Series No. 140 of June 17, 2016) (hereinafter "Regulations");

Having regard to the decree of the Minister of Health dated Jan. 20, 2023, by which Dr. Anna Rosa Marra, effective Jan. 25, 2023, was appointed as a substitute for the director general of the Italian Medicines Agency, pending the implementation of the provisions of ar- ticle 3 of Decree-Law No. 169 of 2022, converted, with amendments, by Law No. 196 of 2022;

Given the Director General's Determination No. 643 of May 28, 2020, by which Dr. Trotta Francesco was appointed as manager of the HTA and drug eco- nomy Sector;

Having regard to the Director General's Determination No. 1568 of December 21, 2021, whereby Dr. Trotta Francesco was delegated, in accordance with Article 10, paragraph 2, letter *e)* of Ministerial Decree No. 245 of September 20, 2004, to sign the determinations of classification and pricing of medicines;

Given the determination of the deputy director general No. 47 of Feb. 9, 2023, by which Dr. Trotta Francesco was confirmed as the delegation of authority to sign the classification and pricing deter- mines of medicines;

Having regard to Act No. 537 of December 24, 1993, concerning
"Corrective Interventions in Public Finance," with special reference to Article 8, Paragraph 10, which provides for the clas- sification of medicines that can be dispensed at the expense of the National Health Service;

Having regard to Law No. 376 of December 14, 2000, on "Di- scipline of health protection of sports activities

and the fight against *doping*."

Having regard to Article 48, Paragraph *33-ter* of Decree Law No. 269 of September 30, 2003, converted, with amendments, by Law No. 326 of November 24, 2003, regarding medicines subject to conditional reimbursability under AIFA monitoring re- gisters;

Having regard to Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of December 12, 2006 on medicinal products for paediatric use;

Having regard to Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of November 13, 2007 on advanced therapy medicinal products, amending Directive 2001/83/EC and Regulation (EC) No. 726/2004;

Having regard to Regulation (EC) No. 726/2004 of the European Parliament and of the Council of March 31, 2004, laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency;

Having regard to Legislative Decree No. 219 of April 24, 2006, re- citing "Implementation of Directive 2001/83/EC (and subsequent amending directives) on a Community code relating to medicinal products for human use."

Given the Ministry of Health Decree of August 2, 2019 on "Criteria and methods by which the Italian Drug Agency determines, through negotiation, the prices of drugs reimbursed by the National Health Service," published in the *Official Gazette of* the Italian Republic, General Series, No. 185 of July 24, 2020;

Having regard to Articles 11 and 12 of Decree-Law No. 158 of September 13, 2012, on "Urgent provisions to promote the development of the country through a higher level of health protection," converted, with amendments, into Law No. 189 of November 8, 2012, as amended and supplemented;

Given Article 17 of Law No. 118 of August 5, 2022, on "Annual Market and Competition Law 2021."

Given the AIFA determination of July 3, 2006, concerning.
"List of class *(a)* medicines reimbursable by the National Health Service (NHS) under Article 48, Paragraph 5 (*c)* of the Decree-Law of September 30, 2003,
No. 269, converted, with amendments, into Law No. 326 of 24 no- vember 2003 (National Pharmaceutical Handbook 2006)," published in the *Official Gazette of* the Italian Repub- blica, General Series, No. 156 of July 7, 2006;

Given the AIFA determination of September 27, 2006, bearing
"Manoeuvre for Governing Con- venzionata and Non-Contracted Pharmaceutical Spending," published in the *Official Gazette of* the Italian Republic, General Series,
No. 227 of September 29, 2006;

Having regard to the application submitted on December 21, 2022, in which the company Rhythm Pharmaceuticals Nether- lands B.V. requested the extension of the te- rapeutic indications under reimbursement for the medicinal product "Imci- vree" (setmelanotide);

Having regard to the opinions of the Scientific and Technical Advisory Commission issued at its meeting on March 28, 2023 and June 7-9, 2023;

Having regard to the application submitted on July 28, 2023, in which the company Rhythm Pharmaceuticals Netherlands
B.V. requested negotiation for the purpose of listing under Law No. 648/96 of the drug IMCIVREE (setmelanotide);

Having regard to the opinion of the Price and Reimbursement Committee rendered at its meeting on October 23-25 and 30, 2023;

Having regard to Resolution No. 45 of December 20, 2023, of the AIFA Board of Directors, adopted on the proposal of the director general, concerning the approval of medicines for marketing authorization and reimbursability by the National Health Service;

Having seen the official records;

Determination:

Art. 1.

Classification for the purpose of reimbursability

The newly authorized therapeutic indication of the medi- cinal IMCIVREE (setmelanotide):

"Imcivree" is indicated for the treatment of obesity and hunger control associated with genetically confirmed Bardet- Biedl syndrome (BBS) in adults and children six years of age and older, and the new therapeutic in- dication of the drug "Imcivree" (setmelanotide) for the purpose of listing under Law No. 648/1996:

"'Imcivree' is indicated for the treatment of obesity and hunger control associated with hypothala- mic acquired obesity (HO) from craniopharyngioma of patients older than six years of age." are reimbursed as follows.

Packaging:

"10 mg / ml - solution for injection - subcu- taneous use- vial (glass) 1 ml" 1 vial - A.I.C.
No. 049605013/E (base 10);

Class of reimbursability: H;

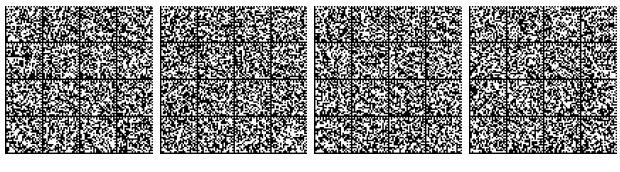
Ex-factory price (excluding VAT): euro 2,750.00;

Retail price (including VAT): euro 4,538.63.

Mandatory discount on the *ex-factory price*, according to the price/volume mechanism, to be given to public health facilities, including pri- vate health facilities accredited with the National Health Service, as per negotiation conditions.

Attribution of therapeutic innovation requirement, in relation to the negotiated therapeutic indication "Imcivree" is indicated for the treatment of obesity and hunger control associated with Bardet-Biedl syndrome (BBS), genetically confirmed in adults and children aged six years and older," from which follows:

The inclusion in the Innovative Medicines Fund o f Article 1, paragraph 401, of Law No. 232/2016 (Budget Law 2017), as amended by Decree-Law No. 73 of May 25, 2021, converted with amendments by the-
Law July 23, 2021, No. 106, (Art. *35-ter*)..;



the economic benefit of the suspension of statutory ri- ductions, as per the AIFA determinations of July 3, 2006 and September 27, 2006, resulting from the recognition of innovativeness;

Inclusion in the regional therapeutic registries within the terms provided for by current legislation (Art. 10, com- munication 2, Decree-Law No. 158/2012, converted, with amendments, into Law No. 189/2012;

Inclusion in the list of innovative drugs pursuant to Article 1, paragraphs 1 and 2, of the agreement signed on November 18, 2010 (Acts Rep. No. 197/CSR) and pursuant to Article 1, paragraphs 401-406 of Law No. 232/2016 (Budget Law 2017), as amended by Decree-Law No. 73 of May 25, 2021, converted with amendments by the-
Law July 23, 2021, No. 106 (Art. *35-ter*).

Confirmation of the therapeutic innovation requirement, in relation to the negotiated therapeutic indication "Imci- vree is indicated for the treatment of obesity and hunger control associated with pro-opiomelanocortin (POMC) deficiency, including PCSK1, with genetically confirmed bi- allelic loss of function, or bi-allelic leptin receptor (LEPR) *deficiency* in adults and children six years of age and older," from which it follows:

The inclusion in the fund for innovative drugs in Article 1, paragraph 401, of Law No. 232/2016 (Budget Law 2017), as amended by Decree-Law No. 73 of May 25, 2021, converted with amendments by the-
Law No. 106 of July 23, 2021 (Art. *35-ter*);

the economic benefit of the suspension of statutory re- ductions, as per the AIFA determinations of July 3, 2006 and September 27, 2006, resulting from the recognition of innovativeness;

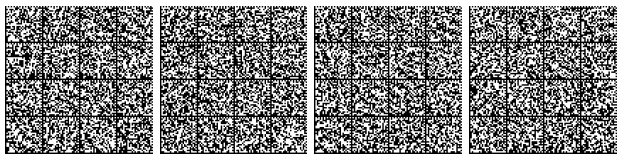
Inclusion in regional treatment plans within the timeframe stipulated by current legislation (Art. 10, com-munity, Decree-Law No. 158/2012, converted, with amendments, into Law No. 189/2012);

The inclusion in the list of innovative drugs pursuant to Article 1, paragraphs 1 and 2, of the agreement signed on November 18, 2010 (Acts Rep. No. 197/CSR) and pursuant to Article 1, paragraphs 401-406 of Law No. 232/2016 (Budget Law 2017), as amended by Decree-Law No. 73 of May 25, 2021, converted with amendments by the-
Law July 23, 2021, No. 106 (Art. *35-ter*).

This confirmation of the requirement of therapeutic innovativeness will have a duration equal to any time remaining from AIFA Determination No. 562/2022 of August 3, 2022, published in the *Official Gazette of* the Italian Republic
No. 200 of August 27, 2022.

The new indication "Imcivree is indicated for the treatment of obesity and hunger control associated with hypothalamic acquired obesity (HO) by craniopharyngeal- but of patients older than six years of age" is negotiated for inclusion in the list established under Law No. 648/1996.

The company, subject to the provisions on stockpile disposal, in compliance with Article 13 of Decree Law No. 35 of April 30, 2019, converted, with amendments, into Law No. 60 of June 25, 2019, undertakes to maintain a constant supply adequate to the needs of the National Health Service.



Validity of the contract:

supplementary agreement of the AIFA determination No. 562/2022 of August 3, 2022, published in the *Official Gazette of* the Italian Republic No. 200 of August 27, 2022.

The parties agree not to automatically renew the agreement, notwithstanding the provisions of current regulations.

Art. 2.

Conditions and methods of use

A registry dedicated to monitoring the use of the drug "Imcivree," based on setmelanotide, is established for the indication eligible for reimbursement:

"Imcivree" is indicated for the treatment of obesity and hunger control associated with genetically confirmed Bardet- Biedl syndrome (BBS) in adults and children aged six years and older.

For the purpose of prescribing and dispensing the medical, physicians and pharmacists attached to the utilization centers specifically identified by the regions will have to fill out the computerized data collection form available upon access through AIFA's institutional website at https://registri.aifa.gov.it

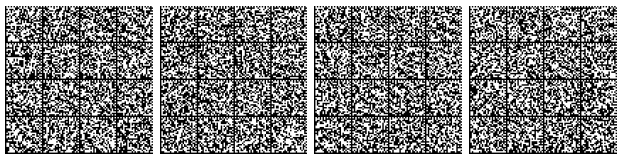
Physicians and pharmacists qualified for access to the AIFA monitoring registry will have to carry out the prescription and dispensing of the medicine in accordance with the eleg- gibility and prescriptive appropriateness criteria reported in the documentation available on the AI- FA institutional portal: https://www.aifa.gov.it/registri-e-piani-terapeutici1

In case of temporary impediment of access to the information systems, licensed physicians and pharmacists will have to secure treatments as of the effective date of this determination. Subsequent to the availability of IT functionality, physicians and pharmacists will still have to enter the data of treatments performed in the aforementioned web platform.

Art. 3.

Classification for supply purposes

The classification for the purpose of supply of the medicine "Imcivree" (setmelanotide) is as follows: medicine subject to a restrictive prescription, saleable to the public on prescription by regio- nally identified centers (RRLs).



Art. 4.

Final Provisions

This determination takes effect on the day following its publication in the *Official Gazette of* the Italian Republic and will be notified to the company holding the marketing authorization.

Rome, January 29, 2024

The executive:
TROTTA

24A00620

DETERMINATION January 29, 2024.

Corrigendum to Aifa Determination No. 516/2023 of July 24, 2023, concerning the reclassification of the medicinal product for human use "Omtisa" in accordance with Article 8, paragraph 10, of Law No. 537 of December 24, 1993. (Determination No. 31/2024).

THE DIRECTOR.
OF THE SECTOR HTA AND DRUG ECONOMICS

Given Article 48 of the Decree-Law of September 30, 2003,
No. 269, on "Urgent provisions to promote development and correct the trend in public accounts," converted, with amendments, into Law No. 326 of Nov. 24, 2003, which established the Italian Drug Agency and, in particular, paragraph 33, which provides for price negotiation for products reimbursed by the National Health Service between the Agency and manufacturers;

Having regard to Decree No. 245 of September 20, 2004, of the Ministry of Health, in consultation with the Ministers of the Civil Service and of Economy and Finance, laying down rules on the organization and operation of the Italian Drug Agency, issued pursuant to Article 48, paragraph 13, above, as amended by Decree No. 53 of the Ministry of Health in consultation with the Ministers of Public Administration and Simplification and of Eco- nomy and Finance of March 29, 2012;

Having regard to the Regulations on Organization, Functioning and Personnel Order of the Italian Medicines Agency, published on the Agency's institutional website (notice in *Official Gazette of* the Italian Republic - General Series No. 140 of June 17, 2016);

Having regard to the decree of the Minister of Health dated January 20, 2023, by which Dr. Anna Rosa Marra, effective January 25, 2023, was appointed as a substitute for the director general of the Italian Drug Agency, pending the implementation of the provisions of Article 3 of Decree-Law No. 169 of 2022, converted, with amendments, by Law No. 196 of 2022;

Given the determination of the director general No. 643 of May 28, 2020, by which Dr. Trotta Francesco was appointed director of the HTA and drug eco- nomy Sector;

Having regard to the Director General's Determination No. 1568 of December 21, 2021, whereby Dr. Trotta Francesco was delegated, in accordance with Article 10, paragraph 2, letter *e)* of Ministerial Decree No. 245 of September 20, 2004, to sign the determinations of classification and pricing of medicines;

Given the determination of the deputy director general No. 47 of Feb. 9, 2023, by which Dr. Trotta Francesco was confirmed as the delegation of authority to sign the classification and pricing deter- mines of medicines;

Having regard to Legislative Decree No. 219 of April 24, 2006, re- citing "Implementation of Directive 2001/83/EC (and subsequent amending directives) on a Community code relating to medicinal products for human use, as amended and supplemented."

Having regard to AIFA Determination No. 516/2023 of July 24, 2023, concerning "Reclassification of the medicinal product for human use "Omtisa," pursuant to Article 8, paragraph 10, of Law No. 537 of December 24, 1993," published in the *Official Gazette of* the Italian Republic, General Series,
No. 185 of August 9, 2023;

Whereas it should be corrected, to delete the period related to the Mandatory Price Discount *ex factory*;

Having seen the Office records;

Determination:

Art. 1.

Corrigendum to AIFA Determination No. 516/2023 of July 24, 2023

AIFA Determination No. 516/2023 of July 24, 2023, regarding "Re-classification of the medicinal product for human use "Omtisa," pursuant to Article 8, paragraph 10, of Law No. 537 of December 24, 1993," published in the *Official Gazette of* the Italian Republic, General Series, No. 185 of August 9, 2023, is corrected in the following terms.

"Compulsory discount on *ex- factory* price, to be pra- cised to public health care facilities, including private health care facilities accredited with the National Health Service, as per negotiation conditions"

Should be removed from the text of the act.

Art. 2.

Final Provisions

This determination will be published in the *Official Gazette of* the Italian Republic and will be notified to the company holding the marketing authorization for the drug.

Rome, January 29, 2024

The executive:
TROTTA

24A00621