SUMMARY OF DECISIONS FROM THE SPANISH INTERMINISTERIAL MEDICINAL PRODUCTS PRICING COMMITTEE (CIPM)

SESSION 203 OF SEPTEMBER 15TH, 2020

October 29th, 2020

INFORMATIVE NOTE OF THE MEETING FROM THE SPANISH INTERMINISTERIAL MEDICINAL PRODUCTS PRINCING COMMITTEE

SESSION 203 OF SEPTEMBER 15th, 2020

For information purposes, this note summarises the **main agreements** established by the Spanish Interministerial Medicinal Products Pricing Committee (CIPM), a collegial body competent in setting the maximum industrial price, gathered on September 15th, 2020.

It is specified that these agreements are not definitive since, prior to the Resolution by the Directorate-General for Basic Portfolio of Services of the National Health System and Pharmacy, the process of allegations is disposed to the Resolution Project by the company, according to the administrative procedure.

The agreements taken in this Committee of September 2020 will not be effective until the corresponding final Resolution is issued by the Directorate-General for Basic Portfolio of Services of the National Health System and Pharmacy and the changes generated by these agreements are included in the corresponding billing Nomenclator.

The agreements differ into two **blocks**: agreements with pricing and reimbursement (approvals) and rejected agreements.

Each block is divided into the following **sections**:

A. New medicinal products: This section includes the agreements related to the inclusion or non-inclusion in the pharmaceutical provision of the National Health System (NHS) of **medicines with new active ingredients or combinations (A.1) and other medicines (A.2)** (this subsection includes, for example, the first generics, first biosimilars and first copies, among others).

B. New indications: This section includes the agreements regarding the inclusion or non-inclusion in the pharmaceutical provision of the NHS of **new indications of medicines that are already included in the pharmaceutical provision of the NHS.**

C. Modifications to the pharmaceutical offering: This section includes the agreements related to alterations in the offer, i.e., to the **modification of reimbursement and price conditions** (price raises or reductions, conditions of prescription and dispensation, exclusion of the provision) of medicines included in the pharmaceutical provision of the NHS.

D. Allegations: This section includes the agreements related to the records (may be new drugs, new indications or alterations of the offer) that have obtained an agreement of acceptance or non-acceptance of the allegations presented by the medicine's laboratory holder object of record.

In the case that the medicines' laboratory holders included in sections A (new medicinal products), B (new indications) and C (modifications to the pharmaceutical offering) do not present allegations and

accept the draft resolution or submit the allegations and these are accepted, reimbursement resolution will be issued.

In the case that the medicines' laboratory holders included in sections A (new medicinal products), B (new indications) and C (modifications to the pharmaceutical offering) present allegations and these are not accepted, an express resolution of non- reimbursement will be issued.

It should be noted that in sections A (new medicinal products), B (new indications) and D (allegations) are included, both in the text of the agreement and in the table that is included in record, the reasons for reimbursement /non- reimbursement, these being those established in article 92 of Royal Legislative Decree 1/2015, of July 24, approving the revised text of the Law on guarantees and rational use of medicines and medical devices through (*Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios*) which medicinal products are financed:

Article 92

a) *Severity, duration, and sequelae of the different pathologies for which they are indicated.*
b) *Specific needs of certain groups.*
c) *Therapeutic and social value of the medicinal product and its incremental clinical benefit, taking into account its cost-effectiveness ratio.*
d) *Rationalisation of public expenditure for pharmaceutical provision and budget impact in the National Health System.*
e) *Existence of medicinal products or other therapeutic alternatives for the same conditions at a lower price or lower treatment cost.*
f) *Degree of innovation of the medicinal product.*

In section C (modifications to the pharmaceutical offering) the criteria for decision-making are those established in articles 93 and 96 of the abovementioned Law.

1. P&R APPROVALS

A. NEW MEDICINAL PRODUCTS

A.1. NEW MEDICINAL PRODUCTS

○ WAKIX®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
BIOPROJET PHARMA	**WAKIX 4,5 MG**	30 film coated tablets	712339	297	a) and c)
BIOPROJET PHARMA	**WAKIX 18 MG**	30 film coated tablets	712096	297	a) and c)

Active substance: Pitolisant. ATC: N07XX11

Authorised therapeutic indication:

Wakix® is indicated in adults for the treatment of narcolepsy with or without cataplexy.

Prescription and dispensation conditions: Medical prescription.

The Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.
- **Restriction of the indication** for the treatment of narcolepsy with cataplexy in adults.
- **Establishment for this medicine of special dispensation conditions** within the scope of the National Health System, consistent with limiting its dispensation, without the need for a visa, to patients not hospitalised in the Pharmacy Services of Hospitals.
- **Annual revision of sales and prices now set**, to ensure that they are within the legally established parameters, and if not, proceed to their adaptation through the corresponding reduction.

○ REFIXIA®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
NOVO NORDISK PHARMA SA	**REFIXIA 1000 UI**	1 vial + 1 prefilled syringe powder and solvent for injectable solution	719687	2543.62	a) and c)
NOVO NORDISK PHARMA SA	**REFIXIA 500 UI**	1 vial + 1 prefilled syringe powder and solvent for injectable solution	719686	1271.81	a) and c)
NOVO NORDISK PHARMA SA	**REFIXIA 2000 UI**	1 vial + 1 prefilled syringe powder and solvent for injectable solution	719685	5087.25	a) and c)

Active substance: Coagulation factor IX. Nonacog beta pegol ATC: B02BD04

Authorised therapeutic indication:

Treatment and prophylaxis of bleeding in patients 12 years and above with haemophilia B (congenital factor IX deficiency).

Prescription and dispensation conditions: Medical prescription. Hospital use.

The Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.

A.2 OTHER MEDICINAL PRODUCTS

○ ROSUVASTATINA / EZETIMIBA

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
STADA, S.L.	**ROSUVASTATIVA / EZETIMIBA STADAGEN 10 MG/10 MG**	30 film coated tablets	727390	17.00	d)
STADA, S.L.	**ROSUVASTATIVA / EZETIMIBA STADAGEN 20 MG/10 MG**	30 film coated tablets	727397	19.68	d)

Active substance: V10BA06 - Rosuvastatina y ezetimiba

Therapeutic indication: Rosuvastatina/Ezetimiba Stadagen is indicated as diet adjuvant for the treatment of primary hypercholesterolemia in adult patients as substitution therapy in adequately controlled patients with monocomponents.

Prescription and dispensation conditions: Medical prescription.

Regarding this medicinal product, the Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.

○ ZAFRIL®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
GEDEON RICTCHER PLC	**ZAFRIL 2 mg, tablets EFG**	28 tablets	727854	6.78	c)

Active substance: G03DB08 – Dienogest.

Therapeutic indication: Treatment of endometriosis.

Prescription and dispensation conditions: Medical prescription.

Regarding this medicinal product, the Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.

○ DEFERASIROX STADA EFG®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
LABORATORIO STADA SL	**DEFERASIROX STADA 90 MG EFG**	30 film coated tablets	728084	99.23	d)
LABORATORIO STADA SL	**DEFERASIROX STADA 360 MG EFG**	30 film coated tablets	728083	396.9	d)

Active substance: V03AC03 – Deferasirox

Authorised therapeutic indication:

Deferasirox is indicated for the treatment of chronic iron overload due to frequent blood transfusions (≥7 ml/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older.

Deferasirox is also indicated for the treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups:

- in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (≥7 ml/kg/month of packed red blood cells) aged 2 to 5 years,

- in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (<7 ml/kg/month of packed red blood cells) aged 2 years and older,

- in adult and paediatric patients with other anaemias aged 2 years and older.

Deferasirox is also indicated for the treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion dependent thalassaemia syndromes aged 10 years and older.

Prescription and dispensation conditions: Medical prescription. Hospital Diagnosis.

Regarding this medicinal product, the Committee **agrees** to the financing of the new indications under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.

○ TOLVAPTAN EFG

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
TEVA PHARMA SL	**TOLVAPTAN TEVA 15 MG + TOLVAPTAN TEVA 45 MG EFG**	56 (28x15 mg + 28x45 mg) tablets	728269	497.28	d)
TEVA PHARMA SL	**TOLVAPTAN TEVA 15 MG + TOLVAPTAN TEVA 45 MG EFG**	56 (28x15 mg + 28x45 mg tablets	728272	497.28	d)
TEVA PHARMA SL	**TOLVAPTAN TEVA 30 MG + TOLVAPTAN TEVA 90 MG EFG**	56 (28x30 mg + 28x90 mg) tablets	728293	621.6	d)
TEVA PHARMA SL	**TOLVAPTAN TEVA 30 MG + TOLVAPTAN TEVA 90 MG EFG**	56 (28x30 mg + 28x90 mg) tablets	728297	621.6	d)

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
TEVA PHARMA SL	**TOLVAPTAN TEVA 30 MG + TOLVAPTAN TEVA 60 MG EFG**	56 (28x30 mg + 28x60 mg) tablets	728262	559.44	d)
TEVA PHARMA SL	**TOLVAPTAN TEVA 30 MG + TOLVAPTAN TEVA 60 MG EFG**	56 (28x30 mg + 28x60 mg) tablets	728258	559.44	d)
TEVA PHARMA SL	**TOLVAPTAN TEVA 15 MG EFG**	7 tablets	728280	139.86	d)
TEVA PHARMA SL	**TOLVAPTAN TEVA 15 MG EFG**	7 tablets	728277	139.86	d)
TEVA PHARMA SL	**TOLVAPTAN TEVA 30 MG EFG**	7 tablets	728265	155.4	d)
TEVA PHARMA SL	**TOLVAPTAN TEVA 30 MG EFG**	7 tablets	728263	155.4	d)

Active substance: C03XA01-Tolvaptan

Therapeutic indication: Tolvaptán Teva is indicated to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease (CKD) stage 1 to 4 at initiation of treatment with evidence of rapidly progressing disease.

Prescription and dispensation conditions: Medical prescription. Hospital diagnosis.

Regarding this medicinal product, the Committee **agrees:**

- **Set the price** of the cited medicine, which is listed in the table above.
- **Establishment for this medicine of special dispensation conditions** within the scope of the National Health System, consistent with limiting its dispensation, without the need for a visa, to patients not hospitalised in the Pharmacy Services of Hospitals.
- ***Restrict its use*** to what is stated in the Conclusions of its Therapeutic Positioning Report. This is: "For adult patients who:
    - They have stage 1-3 of chronic kidney disease at the start of treatment
    - With typical disease observed by means of an image obtained by magnetic resonance or computed tomography, and in which an increase in the total volume of the kidney adjusted for height according to age ranges of 3% per year is expected. The treatment of patients with atypical characteristics should be carried out according to clinical criteria or, if the previous evaluation is not possible, in patients with a kidney diameter> 16.5 cm by ultrasound, as long as the patient's age and the integral clinical evaluation of the same so advises it. Particularly in those young patients who present a renal diameter measured by ultrasound between 13 and 16.5 cm, a renal MRI should be

performed in order to verify compliance with the requirements established in the previous paragraph.

- They do not present a contraindication for the initiation of treatment due to the levels of transaminases or bilirubin. In those patients who evolve to grade 4 renal failure during treatment with tolvaptan, its continuation will be carefully evaluated. The continuation of treatment should also be evaluated individually based on liver monitoring, the clinical situation of each patient and the established therapeutic objectives. It is recommended that the indication for treatment with tolvaptan for ADPKD be restricted to clinical units with experience in the treatment of hereditary kidney diseases. " Likewise, in order to identify the patients who are most likely to benefit from treatment with tolvaptan, the "Recommendations of the Castilian-Astur-Leonese Society of Nephrology for the treatment of patients with autosomal dominant renal polcystosis" should be taken into account

○ TOLVAPTAN EFG

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
TEVA PHARMA SL	**TOLVAPTAN TEVAGEN 30 MG EFG**	10 tablets	728284	351	d)
TEVA PHARMA SL	**TOLVAPTAN TEVAGEN 30 MG EFG**	10 tablets	728282	351	d)
TEVA PHARMA SL	**TOLVAPTAN TEVAGEN 15 MG EFG**	10 tablets	728286	351	d)
TEVA PHARMA SL	**TOLVAPTAN TEVAGEN 15 MG EFG**	10 tablets	728289	351	d)
TEVA PHARMA SL	**TOLVAPTAN TEVAGEN 30 MG EFG**	30 tablets	728626	658.13	d)
TEVA PHARMA SL	**TOLVAPTAN TEVAGEN 30 MG EFG**	30 tablets	728627	658.13	d)
TEVA PHARMA SL	**TOLVAPTAN TEVAGEN 15 MG EFG**	30 tablets	728628	658.13	d)
TEVA PHARMA SL	**TOLVAPTAN TEVAGEN 15 MG EFG**	30 tablets	728624	658.13	d)

Active substance: C03XA01-Tolvaptan

Therapeutic indication: Tolvaptán is indicated for adult patients for the treatment of secondary hyponatremia of the syndrome of inappropriate antidiuretic hormone secretion.

Prescription and dispensation conditions: Medical prescription.

Regarding this medicinal product, the Committee **agrees:**

- **Set the price** of the cited medicine, which is listed in the table above.
- **Establishment for this medicine of special dispensation conditions** within the scope of the National Health System, consistent with limiting its dispensation, to patients not hospitalised in the Pharmacy Services of Hospitals.

○ DARZALEX®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
JANSSEN CILAG S.A.	**DARZALEX 1.800 mg INJECTABLE SOLUTION**	1 vial 15 ml	728747	7142,19	c)

Active substance: L01XC24-DARATUMUMAB

Therapeutic indication:

DARZALEX is indicated:

- in combination with lenalidomide and dexamethasone or with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
- in combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.
- in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.
- as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.

Reimbursed therapeutic indications:

- as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.
- in combination with bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy

- Restrict its use of the association of daratumumab with lenalidomida y dexamethasone (DRd therapy) to patients that have received at least 2 treatments previously (third treatment line).
- In combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Prescription and dispensation conditions: Medical prescription. Hospital Use

Regarding this medicinal product, the Committee **agrees:**

- **Set the price** of the cited medicine, which is listed in the table above.
- **Reimburse** in the same therapeutic indications as the reimbursed ones from the presentations for intravenous administration:
    - as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.
    - in combination with bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy
    - Restrict its use of the association of daratumumab with lenalidomida y dexamethasone (DRd therapy) to patients that have received at least 2 treatments previously (third treatment line).
    - In combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
- Same as reimbursed intravenous presentations, a discount Will be applied in the cost of dispensed units in 6 first treatment cycles of each patient, without the obligation to reach that number of cycles to apply the discount.
- **Annual revision of sales** and prices now set, to ensure that they are within the legally established parameters, and if not, proceed to their adaptation through the corresponding reduction.
- The follow-up and control of the expense caused will be carried out by means of the SEGUIMED computer process and/or any other available one. The laboratory will be obliged to register in this application and to communicate on a monthly basis the timely information regarding the sales made of the drug to the NHS.

○ NYXOID®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
MUNDIPHARMA PHARMACEUTICALS S.L. SOCIEDAD UNIPERSONAL	**NYXOID 1,8MG SOLUCIÓN PARA PULVERIZACIÓN NASAL**	2 envases pulverizadores de 1 dosis	722424	25	a) and c)

Active substance: V03AB15 - Naloxona

Therapeutic indication:

Nyxoid is intended for immediate administration as emergency therapy for known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression in both non-medical and healthcare settings.

Nyxoid is indicated in adults and adolescents aged 14 years and over.

Nyxoid is not a substitute for emergency medical care.

Prescription and dispensation conditions: Medical prescription.

Regarding this medicinal product, the Committee **agrees:**

- **Set the price** of the cited medicine, which is listed in the table above.
- ***General recommendations*** for the use of the drug will be established in the Permanent Pharmacy Commission in coordination with the Government Delegation for the National Plan where the criteria for use are identified for an adequate and homogeneous management of the drug. These recommendations will be adapted to the local environment in each autonomous community
- Its dispensing within the scope of the SNS will be carried out by the hospital pharmacy services or in authorized healthcare centres, under what the competent authority in matters of pharmaceutical provision of each autonomous community, the autonomous cities of Ceuta and Melilla and the Mutual societies establish in the prevention and care programs for opioid dependence.
- The prescription of this medicine is restricted to the medical professionals who are thus defined in the program for the prevention and care of opioid dependence in each autonomous community and autonomous city of Ceuta and Melilla and the Mutual Societies.
- **Annual revision of sales** and prices now set, to ensure that they are within the legally established parameters, and if not, proceed to their adaptation through the corresponding reduction.
- The follow-up and control of the expense caused will be carried out by means of the SEGUIMED computer process and/or any other available one. The laboratory will be obliged to register in this application and to communicate on a monthly basis the timely information regarding the sales made of the drug to the NHS.

○ EMPRESSIN®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
ORPHA DEVEL HANDELS und VERTRIEBS GMBH	**EMPRESSIN 40 UI/2 ml concentrado para perfusión**	10 ampoules	723548	880	a) and c)

Active substance: H01BA01-Argipresina

Therapeutic indication: For the treatment of catecholamine-refractory hypotension associated with septic shock in patients over 18 years of age. Hypotension is considered to be refractory to catecholamines when mean arterial pressure is not restored despite adequate replacement of blood volume and administration of catecholamines.

Prescription and dispensation conditions: Hospital Use.

Regarding this medicinal product, the Committee **agrees:**

- **Set the price** of the cited medicine, which is listed in the table above.
- **Annual revision of sales** and prices now set, to ensure that they are within the legally established parameters, and if not, proceed to their adaptation through the corresponding reduction.

C. ALTERATIONS OF PHARMACEUTICAL OFFERING

○ CUPRIPEN®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	ACTUAL PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REVIEW
LABORATORIOS RUBIO SA	**CUPRIPEN 250mg**	30 hard capsules	723293	9.59	13.17	Article 96.2

Active substance: M01CC01 - penicilamina

Therapeutic indication: Treatment of rheumatoid arthritis including juvenile forms when the disease is resistant to other therapeutic procedures. Lead and other heavy metal poisoning. Hepatolenticular degeneration (Wilson's disease) and chronic cystinuria

Prescription and dispensation conditions: medical prescription.

Regarding this medicinal product, the Committee **agrees:**

- **Modify the price** of the cited medicinal product in the terms that appears related in the previous table. Motivated by the change in the economic, technical and sanitary circumstances from the moment when the current price was set.

○ HYDRAPRES INYECTABLE®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	ACTUAL PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REVIEW
LABORATORIOS RUBIO SA	**HYDRAPRES 20 mg**	50 ampoules injectable solution	95947	9.54	11.64	Article 96.2

Active substance: C02DB02 - Hidralazina

Therapeutic indication: Severe essential hypertension, when the oral route is not possible, or it is urgently necessary to lower blood pressure. Preeclampsia and eclampsia.

Prescription and dispensation conditions: medical prescription. Hospital Use

Regarding this medicinal product, the Committee **agrees:**

- **Modify the price** of the cited medicinal product in the terms that appears related in the previous table. Motivated by the change in the economic, technical and sanitary circumstances from the moment when the current price was set, the therapeutic value of this medicine.

○ NEOSTIGMINA BRAUN 0,5 MG/ML

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	ACTUAL PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REVIEW
B. BRAUN MEDICAL, S.A.	**NEOSTIGMINA BRAUN 0,5 MG/ML**	10 ampoules 5 ml	651976	4,21	5,26	Article 96.2
B. BRAUN MEDICAL, S.A.	**NEOSTIGMINA BRAUN 0,5 MG/ML**	10 ampoules 1 ml	793406	1,32	-	-

Active substance: N07AA01 - Neostigmina

Therapeutic indication: -

- Reversal of neuromuscular blockade by non-depolarizing curarizes after surgery.

- Diagnosis and treatment of myasthenia gravis.

- Prevention and treatment of intestinal atony and urinary retention in the postoperative period.

Prescription and dispensation conditions: medical prescription.

Regarding this medicinal product, the Committee **agrees:**

- **Modify the price** of the presentation with NC 651976 in the terms that appears related in the previous table motivated by the change in the economic, technical and sanitary circumstances.
- Regarding the presentation with NC 793406, ex-factory price does not modify since it is no commercialised.

○ ADRENALINA B. BRAUN

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	ACTUAL PRICE (€)	CRITERIA FOR THE REVIEW
B. BRAUN MEDICAL, S.A.	**ADRENALINA B. BRAUN 1 mg/ml**	10 x 1 ml injectable solution	658637	2.5	Article 92

Active substance: C01CA24 - Epinefrina.

Therapeutic indication: Adrenalina B. Braun 1 mg/ml injectable solution is indicated in the following situations:

• Spasm of the airways in acute asthma attacks.

• Quick relief from allergic reactions to drugs or other substances.

• Emergency treatment of anaphylactic shock.

Prescription and dispensation conditions: medical prescription.

Regarding this medicinal product, the Committee **agrees:**

- Change in dispensing conditions, removing *cupon precinto* and going to hospital dispensation.

○ POLIBUTIN

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CURRENT PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
DESMA LABORATORIO FARMACEUTICO, S.L	**POLIBUTIN Oral suspension**	Bottle 250 ml	808360	1.83	2.20	Article 96.2

Active substance: A03AA05 - Trimebutina

Therapeutic indication:

-Gastritis and vomiting associated with GI ulcer, pyloric spasm

-Irritable bowel syndrome

-Biliary dyskinesia

-Postoperative nausea and vomiting

-Adjuvant treatment in infantile gastroenteritis

Prescription and dispensation conditions: medical prescription.

Regarding this **medicinal product, the Committee agrees** to:

- **Modify the price** of the cited medicine, which is listed in the table above. The modification is based on the change of economic, technical and sanitary circumstances and the therapeutic value of this classic medicine.

○ GANFORT

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CURRENT PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
ALLERGAN. SAE	**GANFORT 0,3 mg/ml +5 mg/ml**	3 eye drops solution	654561	14.87	11.9	Article 96.2
ALLERGAN. SAE	**GANFORT 0,3 mg/ml +5 mg/ml**	30 packs monodosis X 0,4 ml eye drops solution	699328	17.9	14.84	Article 96.2

Active substance: S01ED51 – bimatoprost + timolol

Therapeutic indication: Reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are not sufficiently sensitive to topical beta-blockers, or prostaglandin analogues.

Prescription and dispensation conditions: Medical prescription.

Regarding this **medicinal product, the Committee agrees** to:

- **Modify the price** of the cited medicine, which is listed in the table above. The modification is based on the change of economic, technical and sanitary circumstances and the medicine's therapeutic value.

- Annual revision of sales and prices now set, to ensure that they are within the legally established parameters, and if not, proceed to their adaptation through the corresponding reduction

○ BOI-K

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CURRENT PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
IONFARMA, S.L	**BOI-K, effervescent tablets**	50 tablets	700665	2.27	2.55	Article 96.2

Active substance: A12BA04 - Bicarbonato de potasio; ácido ascórbico

Therapeutic indication: Treatment and prophylaxis of hypokalaemia in situations such as:

• Loss of potassium caused by treatment with diuretics, corticosteroids, and derivatives.

• Loss of potassium caused by vomiting, diarrhoea, kidney problems, hyperaldosteronism, intense sweating.

• Situations in which there is a deficit in potassium intake, such as: malnutrition states, deficient diets.

Situations in which an additional intake of vitamin C is necessary

Prescription and dispensation conditions: medical prescription.

Regarding this **medicinal product, the Committee agrees** to:

- **Modify the price** of the cited medicine, which is listed in the table above. The modification is based on the nature of the medicinal product, the high production plasma cost, the medicine's therapeutic value and the lack of alternatives for the same indication.

○ DOGMATIL

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CURRENT PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
SANOFI AVENTIS, S.A	**DOGMATIL 50 mg/ml**	12 ampoules 2 ml injectable solution	700622	2.88	3.96	Article 96.2

Active substance: N05AL01- sulpirida

Therapeutic indication:

-Treatment of depressive disorders with psychotic symptoms in combination with antidepressants when treatment with antidepressants alone has been ineffective and for the treatment of other severe forms of depression resistant to antidepressants.

-Treatment of vertigo in cases in which there is no response to the usual antivertiginous treatment.

-Treatment of acute and chronic psychoses.

Schizophrenia, chronic delusions, autism

Serious behavioural disorders. Neurotic states with inhibition and depression

Prescription and dispensation conditions: Medical prescription.

Regarding this **medicinal product, the Committee agrees** to:

- **Modify the price** of the cited medicine, which is listed in the table above. The modification is based on the change of economic, technical and sanitary circumstances and the medicine's therapeutic value.

○ OMPRANYT ®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CURRENT PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
LABORATORIOS BIAL, S.A.	**OMPRANYT 20 mg CAPSULES**	28 capsules	650576	1.55	Article 93
LABORATORIOS BIAL, S.A.	**OMPRANYT 20 mg CAPSULES**	500 capsules	647115	21.25	Article 93
LABORATORIOS BIAL, S.A.	**OMPRANYT 20 mg CAPSULES**	14 capsules	884353	1.6	Article 93

Active substance: A02BC01 - Omeprazol

Therapeutic indication:

• Treatment of duodenal ulcers

• Prevention of recurrence of duodenal ulcers

• Treatment of gastric ulcers

• Prevention of gastric ulcer recurrence

• In combination with appropriate antibiotics, eradication of Helicobacter pylori (H. Pylori) in peptic ulcers

• Treatment of gastric and duodenal ulcers associated with NSAIDs

• Prevention of gastric and duodenal ulcers associated with NSAIDs in patients at risk

• Treatment of reflux esophagitis

• Long-term management of cured gastroesophageal reflux disease

• Treatment of symptomatic gastroesophageal reflux disease

• Treatment of Zollinger-Ellison syndrome Pediatric use:

Children over one year of age and weighing = 10 kg

• Treatment of reflux esophagitis

• Symptomatic treatment of heartburn and acid regurgitation in gastroesophageal reflux disease.

Prescription and dispensation conditions: medical prescription.

Regarding this **medicinal product, the Committee agrees** to propose to General Directorate the acceptance of exclusion from the NHS taking into account that there are reimbursed alternatives.

D. ALLEGATIONS

○ METASEDIN

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CURRENT PRICE (€)	NEW PRICE (€)	CRITERIA FOR REVIEW
ESTEVE PHARMACEUTICALS, S.A.	**METASEDIN 5 MG**	20 tablets	700636	1.55	1.55	Article 96.2
ESTEVE PHARMACEUTICALS, S.A.	**METASEDIN 5 MG**	800 tablets	604777	56	56.15	Article 96.2
ESTEVE PHARMACEUTICALS, S.A.	**METASEDIN 30 MG**	800 tablets	741249	140.19	141.12	Article 96.2
ESTEVE PHARMACEUTICALS, S.A.	**METASEDIN 40 MG**	800 tablets	741413	167.96	169.2	Article 96.2

Active substance: N07BC02 - Metadona

Therapeutic indication: severe pain of any etiology. Post-operative, post-traumatic, neoplastic, neuritic pain, due to burns, as long as they do not respond to minor analgesics. Treatment of the withdrawal syndrome to narcotics

Prescription and dispensation conditions: medical prescription.

Regarding this medicinal product, once allegations have been studied, the Committee agrees to accept partially presented allegations and send a new resolution project and:

- **Modify the price** of the cited medicine, which is listed in the table above. The modification is based on the change of economic, technical and sanitary circumstances and the medicine's therapeutic value
- With respect to the presentation with CN 700636, considering the price increase suffered by the mg of raw material, and translating this increase on the cost of the tablet, the current price is not modified according to the rounding rule established in Law 46/1998.

○ SINOGAN INYECTABLE

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CURRENT PRICE (€)	NEW PRICE (€)	CRITERIA FOR REVIEW
SANOFI AVENTIS SA	**SINOGAN 25 mg/ml**	10 ampoules 1 ml injectable solution	973743	1.45	1.81	Article 96.2

Active substance: N05AA02 - Levomepromazina

Therapeutic indication: Schizophrenia, transient acute psychoses and paranoid states including manic psychoses, organic psychoses, and short-term treatment of prominent symptoms of psychosis as part of a personality disorder. Adjuvant treatment for the relief of delirium, agitation, nervousness, and confusion, associated with pain in the terminal phase.

Prescription and dispensation conditions: medical prescription.

Regarding this medicinal product the Committee **agrees**:

- **Modify the price** of the cited medicine, which is listed in the table above. The modification is based on the change of economic, technical and sanitary circumstances and the medicine's therapeutic value

2. P&R REJECTIONS

A. NEW MEDICINAL PRODUCTS

The **non-inclusion** in the pharmaceutical provision of the NHS of the medicinal products is agreed:

○ FENTANILO STADA EFG COMPRIMIDOS BUCALES

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
LABORATORIO STADA SL	**FENTANILO STADA 100 MICROGRAMOS EFG**	4 buccal tablets	727223	d)
LABORATORIO STADA SL	**FENTANILO STADA 100 MICROGRAMOS EFG**	28 buccal tablets	727224	d)
LABORATORIO STADA SL	**FENTANILO STADA 200 MICROGRAMOS EFG**	4 buccal tablets	727225	d)
LABORATORIO STADA SL	**FENTANILO STADA 200 MICROGRAMOS EFG**	28 buccal tablets	727226	d)
LABORATORIO STADA SL	**FENTANILO STADA 400 MICROGRAMOS EFG**	4 buccal tablets	727227	d)
LABORATORIO STADA SL	**FENTANILO STADA 400 MICROGRAMOS EFG**	28 buccal tablets	727228	d)
LABORATORIO STADA SL	**FENTANILO STADA 600 MICROGRAMOS EFG**	4 buccal tablets	727229	d)
LABORATORIO STADA SL	**FENTANILO STADA 600 MICROGRAMOS EFG**	28 buccal tablets	727230	d)

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
LABORATORIO STADA SL	**FENTANILO STADA 800 MICROGRAMOS EFG**	4 buccal tablets	727232	d)
LABORATORIO STADA SL	**FENTANILO STADA 800 MICROGRAMOS EFG**	28 buccal tablets	727231	d)

Active substance: N02AB03 - Fentanilo

Therapeutic indication: Indicated for the treatment of breakthrough pain (BTP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. BTP is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain.

Patients receiving maintenance opioid therapy are those who are taking at least 60 mg of oral morphine daily, at least 25 micrograms of transdermal fentanyl per hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.

Prescription and dispensation conditions: medical prescription narcotics.

Regarding to this medicinal product, the Committee **agrees to propose to the General Directorate of Pharmacy the non-inclusion** of the medicine in the pharmaceutical benefit of the NHS, since it does not meet the criteria agreed by CIPM for the reimbursement of this medicinal products.

○ DEFERASIROX STADA EFG

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
LABORATORIO STADA SL	**DEFERASIROX STADA 180 MG film coated tablets EFG**	30 film coated tablets	728082	d)

Active substance: V03AC03 - Deferasirox

Therapeutic indication: Deferasirox is indicated for the treatment of chronic iron overload due to frequent blood transfusions (≥7 ml/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older.

Deferasirox is also indicated for the treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups:

- in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (≥7 ml/kg/month of packed red blood cells) aged 2 to 5 years,

- in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (<7 ml/kg/month of packed red blood cells) aged 2 years and older,

- in adult and paediatric patients with other anaemias aged 2 years and older.

Deferasirox is also indicated for the treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion dependent thalassaemia syndromes aged 10 years and older.

Prescription and dispensation conditions: medical prescription. Hospital Diagnosis.

Regarding to this medicinal product, the **Committee agrees to propose to the General Directorate of Pharmacy the non-inclusion** of the medicine in the pharmaceutical benefit of the NHS, since the company did not request price for this dose and the treatment is covered with the reimbursement of the doses of 90 and 360 mg.

○ EYLEA®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
BAYER HISPANIA SL	**Eylea 40mg/ml injectable solution**	1 prefilled syringe	728082	d)

Active substance: S01LA05 - Aflibercept

Therapeutic indication: Eylea is indicated for adults for the treatment of:

- neovascular (wet) age-related macular degeneration (AMD)

- visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO)

- visual impairment due to diabetic macular oedema (DME)

- visual impairment due to myopic choroidal neovascularisation (myopic CNV).

Prescription and dispensation conditions: Hospital Use.

Regarding to this medicinal product, the **Committee agrees to propose to the General Directorate of Pharmacy the non-inclusion** of the medicine in the pharmaceutical benefit of the NHS considering the existence of medicinal products or therapeutic alternatives for the same diseases at a lower cost of treatment. Moreover, rationalization of public expenditure has been taken into account.

○ ALKINDI®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
DIURNAL EUROPE BV	**ALKINDI 0,5 MG**	50 capsules	721441	e)
DIURNAL EUROPE BV	**ALKINDI 1 MG**	50 capsules	721442	e)
DIURNAL EUROPE BV	**ALKINDI 2 MG**	50 capsules	721443	e)
DIURNAL EUROPE BV	**ALKINDI 5 MG**	50 capsules	721444	e)

Active substance: H02AB09 -Hidrocortisona

Therapeutic indication: Replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to < 18 years old).

Prescription and dispensation conditions: Medical prescription.

Regarding to this medicinal product, the **Committee agrees to propose to the General Directorate of Pharmacy the non-inclusion** of the medicine in the pharmaceutical benefit of the NHS considering the existence of medicinal products or therapeutic alternatives for the same diseases at a lower cost of treatment.

○ ELMIRON®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
LACER SA	**ELMIRON**	90 capsules	726353	d)

Active substance: G04BX15 - Pentosan polisulfato de sodio

Therapeutic indication: Elmiron is indicated for the treatment of bladder pain syndrome characterized by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition.

Prescription and dispensation conditions: Medical prescription.

Regarding to this medicinal product, the **Committee agrees to propose to the General Directorate of Pharmacy the non-inclusion** of the medicine in the pharmaceutical benefit of the NHS taking into account the uncertainties regarding the therapeutic value and rationalization of public expenditure and budget impact.

○ MEPSEVII®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
ULTRAGENYX GERMANY GMBH	**MEPSEVII 2 mg/ml**	1 vial solution for perfusion	723571	d)

Active substance: A16AB18- Vestronidasa alfa

Therapeutic indication: Treatment of non-neurological manifestations of Mucopolysaccharidosis VII (MPS VII; Sly syndrome).

Prescription and dispensation conditions: Hospital Use.

Regarding to this medicinal product, the **Committee agrees to propose to the General Directorate of Pharmacy the non-inclusion** of the medicine in the pharmaceutical benefit of the NHS taking into account the high uncertainty in it efficacy and rationalization of public expenditure and budget impact.

B. NEW INDICATIONS

○ ORENCIA®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
BRISTOL-MYERS SQUIBB, S.A.	**ORENCIA 125 mg**	4 prefilled syringes 1 ml	693932	e)
BRISTOL-MYERS SQUIBB, S.A.	**ORENCIA 125 mg**	4 prefilled cartridges 1 ml	706835	e)
BRISTOL-MYERS SQUIBB, S.A.	**ORENCIA 250 mg**	Powder for solution for perfusion 1 vial	659170	e)

Active substance: L04AA24- ABATACEPT

Authorized therapeutic indications:

Rheumatoid arthritis

ORENCIA, in combination with methotrexate, is indicated for:

- the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a tumour necrosis factor (TNF)-alpha inhibitor.
- the treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate.

A reduction in the progression of joint damage and improvement of physical function have been demonstrated during combination treatment with abatacept and methotrexate.

Psoriatic arthritis

ORENCIA, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients when the response to previous DMARD therapy including MTX has been inadequate, and for whom additional systemic therapy for psoriatic skin lesions is not required.

Polyarticular juvenile idiopathic arthritis

ORENCIA in combination with methotrexate is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA) in paediatric patients 6 years of age and older who have had an inadequate response to previous DMARD therapy.

ORENCIA can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate.

Financed therapeutic indications:

Rheumatoid arthritis

ORENCIA, in combination with methotrexate, is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a tumour necrosis factor (TNF)-alpha inhibitor.

Polyarticular juvenile idiopathic arthritis

ORENCIA in combination with methotrexate is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA) in paediatric patients 6 years of age and older who have had an inadequate response to previous DMARD therapy.

ORENCIA can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate.

Therapeutic indications object for this report:

Rheumatoid arthritis

ORENCIA, in combination with methotrexate, is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a tumour necrosis factor (TNF)-alpha inhibitor.

Prescription and dispensation conditions: medical prescription. Hospital Diagnosis.

Regarding to this medicinal product, the **Committee agrees to propose to the General Directorate of Pharmacy the non-inclusion** of this new indication in the pharmaceutical benefit of the NHS taking into account the existence of medicinal products and therapeutic alternatives for the same disease at a lower treatment cost.

○ LONSURF®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
LABORATORIOS SERVIER SL	**LONSURF 15 mg/6,14 mg**	20 film coated tablets	711118	b) and d)
LABORATORIOS SERVIER SL	**LONSURF 15 mg/6,14 mg**	60 film coated tablets	711120	b) and d)
LABORATORIOS SERVIER SL	**LONSURF 20 mg/8,19 mg**	20 film coated tablets	711119	b) and d)
LABORATORIOS SERVIER SL	**LONSURF 20 mg/8,19 mg**	60 film coated tablets	711121	b) and d)

Active substance: TRIFLURIDINA Y TIPIRACILO - L01BC59

Authorized therapeutic indications:

Colorectal cancer

Lonsurf is indicated as monotherapy for the treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents.

Gastric cancer

Lonsurf is indicated as monotherapy for the treatment of adult patients with metastatic gastric cancer including adenocarcinoma of the gastroesophageal junction, who have been previously treated with at least two prior systemic treatment regimens for advanced disease.

Financed therapeutic indications:

Colorectal cancer

Lonsurf is indicated as monotherapy for the treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents.

Therapeutic indications object for this report:

Gastric cancer

Lonsurf is indicated as monotherapy for the treatment of adult patients with metastatic gastric cancer including adenocarcinoma of the gastroesophageal junction, who have been previously treated with at least two prior systemic treatment regimens for advanced disease

Prescription and dispensation conditions: medical prescription. Hospital Diagnosis.

Regarding to this medicinal product, the **Committee agrees to propose to the General Directorate of Pharmacy the non-inclusion** of this new indication in the pharmaceutical benefit of the NHS taking into account the incremental clinical benefit as well rationalization of public expenditure and budget impact criteria.

○ STIVARGA®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
BAYER HISPANIA SL	**STIVARGA 40mg**	3x28 film coated tablets	699574	b) and d)

Active substance: L01XE21 - REGORAFENIB

Authorized therapeutic indications:

metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies. These include fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy.

unresectable or metastatic gastrointestinal stromal tumours (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib

hepatocellular carcinoma (HCC) who have been previously treated with sorafenib

Financed therapeutic indications:

metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies. These include fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy.

unresectable or metastatic gastrointestinal stromal tumours (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib

Therapeutic indications object for this report:

hepatocellular carcinoma (HCC) who have been previously treated with sorafenib

Prescription and dispensation conditions: medical prescription. Hospital Diagnosis. Hospital dispensation

Regarding to this medicinal product, the **Committee agrees to propose to the General Directorate of Pharmacy the non-inclusion** of this new indication in the pharmaceutical benefit of the NHS sice there are no changes from previous agreements related to this indication. The incremental clinical benefit as well rationalization of public expenditure and budget impact criteria has also been considered.

C. ALTERATIONS OF THE OFFER

○ BOI-K

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
IONFARMA, S.L	**BOI-K**	20 effervescent tablets	700664	Article 96.2

Active substance: A12BA04 - Bicarbonato de potasio; ácido ascórbico

Therapeutic indication:

Treatment and prophylaxis of hypokalaemia in situations such as:

• Loss of potassium caused by treatment with diuretics, corticosteroids, and derivatives.

• Loss of potassium caused by vomiting, diarrhoea, kidney problems, hyperaldosteronism, intense sweating.

• Situations in which there is a deficit in potassium intake, such as: malnutrition states, deficient diets.

Situations in which an additional intake of vitamin C is necessary

Prescription and dispensation conditions: medical prescription.

Regarding this medicinal product, the Committee does not amend the decision to finance the medicinal product since there are therapeutic alternatives at a lower cost.

D) ALLEGATIONS

○ MEKINIST®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR REIMBURSEMENT
NOVARTIS FARMACEUTICA S.A.	**MEKINIST 0,5 MG**	30 film coated tablets	707728	d)
NOVARTIS FARMACEUTICA S.A.	**MEKINIST 2 MG**	30 film coated tablets	707730	d)

Active substance: Trametinib L01XE25

Authorized therapeutic indications:

Trametinib as monotherapy or in combination with dabrafenib is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. Trametinib in combination with dabrafenib is indicated for the adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection.

Trametinib in combination with dabrafenib is indicated for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600 mutation

Financed therapeutic indications:

Trametinib as monotherapy or in combination with dabrafenib is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.

Therapeutic indications object for this report:

Trametinib in combination with dabrafenib is indicated for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600 mutation

Prescription and dispensation conditions: medical prescription. Hospital diagnosis

Regarding these medicinal products, the Committee, after consultation, proposes not to accept the allegations and propose to DG the no reimbursement of the new indication, considering that there are no changes from the previous agreement of the committee.

It has been considered the rationalization of public expenditure; the high budget impact driven through the high treatment cost. These are some of the legal criteria established for selective reimbursement of medicinal product necessary for the sustainability of the system.

○ TAFINLAR®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR REIMBURSEMENT
NOVARTIS FARMACEUTICA S.A.	**TAFINLAR 50mg**	28 hard capsules	701613	d)
NOVARTIS FARMACEUTICA S.A.	**TAFINLAR 75mg**	28 hard capsules	699781	d)

Active substance: L01XE23 – Dabrafenib

Authorized therapeutic indications:

Dabrafenib as monotherapy or in combination with trametinib is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. Dabrafenib in combination with trametinib is indicated for the adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection.

Dabrafenib in combination with trametinib is indicated for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600 mutation

Financed therapeutic indications:

Dabrafenib as monotherapy or in combination with trametinib is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.

Therapeutic indications object for this report:

Dabrafenib in combination with trametinib is indicated for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600 mutation

Prescription and dispensation conditions: medical prescription. Hospital diagnosis

Regarding these medicinal products, the Committee, after consultation, proposes not to accept the allegations and propose to DG the no reimbursement of the new indication, considering that there are no changes from the previous agreement of the committee.

It has been considered the rationalization of public expenditure; the high budget impact driven through the high treatment cost. These are some of the legal criteria established for selective reimbursement of medicinal product necessary for the sustainability of the system.

○ CAELYX®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR EXCLUSION
JANSSEN CILAG SA	**CAELYX PEGYLATED LIPOSOMAL 2 MG/ML SOLUTION FOR PERFUSION**	1 injectable solution	674127	92.c

Active substance: L01DB01 – Doxorubicina hidrocloruro

Authorized therapeutic indications: Caelyx is indicated for:

As monotherapy for patients with metastatic breast cancer, where there is an increased cardiac risk.
- For treatment of advanced ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen.
- In combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.
- For treatment of AIDS-related Kaposi's sarcoma (KS) in patients with low CD4 counts (< 200 CD4 lymphocytes/mm3) and extensive mucocutaneous or visceral disease.
Caelyx pegylated liposomal may be used as first-line systemic chemotherapy, or as second line chemotherapy in AIDS-KS patients with disease that has progressed with, or in patient's intolerant to, prior combination systemic chemotherapy comprising at least two of the following agents: a vinca alkaloid, bleomycin and standard doxorubicin (or another anthracycline).

Prescription and dispensation conditions: medical prescription.

Consulted the committee, manifests the non-acceptance of allegations and proposes to the DG the non-acceptance of the exclusion of the medicinal product Caelyx from the NHS, considering its therapeutic utility, its market share and for health and social reasons compromises the current treatment of many patients.

○ FENTANILO ARISTO EFG BUCCAL TABLETS

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR REIMBUSEMENT
ARISTO PHARMA IBERIA SL	**FENTANILO ARISTO 100 MICROGRAMOS BUCCAL TABLETS EFG**	4 buccal tablets	727486	d)

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR REIMBUSEMENT
ARISTO PHARMA IBERIA SL	**FENTANILO ARISTO 100 MICROGRAMOS BUCCAL TABLETS EFG**	28 buccal tablets	727488	d)
ARISTO PHARMA IBERIA SL	**FENTANILO ARISTO 200 MICROGRAMOS BUCCAL TABLETS EFG**	4 buccal tablets	727489	d)
ARISTO PHARMA IBERIA SL	**FENTANILO ARISTO 200 MICROGRAMOS BUCCAL TABLETS EFG**	28 buccal tablets	727490	d)
ARISTO PHARMA IBERIA SL	**FENTANILO ARISTO 400 MICROGRAMOS BUCCAL TABLETS EFG**	4 buccal tablets	727491	d)
ARISTO PHARMA IBERIA SL	**FENTANILO ARISTO 400 MICROGRAMOS BUCCAL TABLETS EFG**	28 buccal tablets	727492	d)
ARISTO PHARMA IBERIA SL	**FENTANILO ARISTO 600 MICROGRAMOS BUCCAL TABLETS EFG**	4 buccal tablets	727493	d)
ARISTO PHARMA IBERIA SL	**FENTANILO ARISTO 600 MICROGRAMOS BUCCAL TABLETS EFG**	28 buccal tablets	727494	d)
ARISTO PHARMA IBERIA SL	**FENTANILO ARISTO 800 MICROGRAMOS BUCCAL TABLETS EFG**	4 buccal tablets	727495	d)
ARISTO PHARMA IBERIA SL	**FENTANILO ARISTO 800 MICROGRAMOS BUCCAL TABLETS EFG**	28 buccal tablets	727496	d)

Active substance: N02AB03 - Fentanilo

Authorized therapeutic indications: Indicated for the treatment of breakthrough pain (BTP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. BTP is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain.

Patients receiving maintenance opioid therapy are those who are taking at least 60 mg of oral morphine daily, at least 25 micrograms of transdermal fentanyl per hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.

Prescription and dispensation conditions: medical prescription of narcotics.

Regarding these medicinal products, the Committee agrees the non-acceptance of the allegations and proposes to DG the no reimbursement of the medicinal product, since it does not meet the criteria agreed by CIPM for the reimbursement of these medicinal products.

○ HYDRAPRES COMPRIMIDOS

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR REVIEW
LABORATORIOS RUBIO SA	**HYDRAPRES 50 mg tablets**	30 tablets	723294	Article 96.2
LABORATORIOS RUBIO SA	**HYDRAPRES 25 mg tablets**	30 tablets	723295	Article 96.2

Active substance: C02DB02 - Hidralazina

Authorized therapeutic indications:

Adults Moderate to severe hypertension in combination with other antihypertensive agents.

Due to its complementary mechanisms of action, the combination of hydralazine with beta-blockers and diuretics makes it possible to achieve antihypertensive efficacy at lower doses and to reduce some effects of hydralazine such as reflex tachycardia and oedema.

Chronic moderate to severe congestive heart failure as add-on medication together with long-acting nitrates in patients who do not respond adequately to conventional diuretic and digitalis treatment.

Prescription and dispensation conditions: medical prescription. TLD

Regarding these medicinal products, the Committee agrees the non-acceptance of the allegations and:

Not modifying the price of the medicinal product since it has not been accredited changes in economic, technical or health circumstances or in the evaluation of therapeutic utility from the moment of price setting

○ ZUTECTRA

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR EXCLUSION
BIOTEST MEDICAL SL	**ZUTECTRA 500 UI INJECTABLE SOLUTION IN PREFILLED SYRINGE**	5 injetable solutions	665954	92.c

Active substance: J06BB04 - Inmunoglobulina antihepatitis B

Authorized therapeutic indications:

Prevention of hepatitis B virus (HBV) re-infection in HBsAg and HBV-DNA negative adult patients at least one week after liver transplantation for hepatitis B induced liver failure. HBV-DNA negative status should be confirmed within the last 3 months prior to OLT. Patients should be HBsAg negative before treatment start.

The concomitant use of adequate virostatic agents should be considered as standard of hepatitis B reinfection prophylaxis.

Prescription and dispensation conditions: medical prescription.

Consulted the committee, manifests the non-acceptance of allegations and proposes to the DG the non-acceptance of the exclusion of the medicinal product from the NHS, considering there are few alternatives reimbursed with the same active ingredient and it cannot be guaranteed the adequate supply to patients.

○ HEPARINA SODICA

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR EXCLUSION
ROVI, S.A.	**HEPARINA SODICA ROVI 5000 UI/ml**	100 vials of 5 ml injectable solution	641639	92.c
ROVI, S.A.	**HEPARINA SODICA ROVI 1000 UI/ml**	100 vials of 5 ml injectable solution	641647	92.c

Active substance: B01AB01 - Heparina

Authorized therapeutic indications:

-Treatment and prevention of venous thromboembolic disease: deep vein thrombosis, and pulmonary thromboembolism.

-Treatment and prevention of peripheral arterial thromboembolism.

-Treatment of coronary disease: unstable angina and acute myocardial infarction.

-Prevention of thrombosis in the extracorporeal circuit during cardiac and vascular surgery and hemodialysis

ROVI sodium heparin is indicated in the pediatric population from 28 days of birth and in adults.

Prescription and dispensation conditions: medical prescription.

Consulted the committee, manifests the non-acceptance of allegations and proposes to the DG the non-acceptance of the exclusion of the medicinal product from the NHS, considering there are few alternatives reimbursed with the same active ingredient and it cannot be guaranteed the adequate supply to patients.