

GM/MS' ORDINANCE #2,261, from December 8, 2023

Establishes the Matrix of Productive and Technological Challenges in Healthcare.

THE MINISTER OF HEALTH, in the use of the powers conferred onto her by Article 87, Sole Paragraph, Items I and II, of the Brazilian Constitution, and considering Article 2, Paragraph 2 of Decree #11,715, of September 26, 2023, and Article 8 of Annex CVII to Consolidation Ordinance #5, of September 28, 2017, resolves:

Article 1. This Ordinance establishes the healthcare challenges and the productive and technological solutions for the Brazilian Public Healthcare System (SUS) presented in the Matrix of Productive and Technological Challenges in Healthcare in accordance with the implementation of the National Strategy for the Development of the Economic-Industrial Health Complex provided for in Decree #11,715, of September 26, 2023, pursuant to Article 8 of Annex CVII of Consolidated Ordinance #5, of September 28, 2017.

Paragraph 1. Matrix brings SUS' priority demands which will guide the National Strategy for the Development of the Economic-Industrial Health Complex, in accordance with the Sole Paragraph of the Article 2 of Decree #11,715, of 2023.

Paragraph 2. Within the scope of the Ministry of Health, Matrix will guide the following programs among others:

- I – Product Development Partnerships Program – PDP;
- II – Local Development and Innovation Program – PDIL;
- III – Preparation of Vaccines, Serums, and Blood Derivatives Program – PPVACSH;
- IV – Production and Technological Development for Neglected Populations and Diseases Program – PPDN;
- V – Assistance Modernization and Innovation Program – PMIA; and
- VI – Expansion and Modernization of Infrastructure of the Health Economic-Industrial Complex Program – PDCEIS.

Article 2. Matrix referred to in article 1 of this Ordinance is made up of healthcare challenges and productive and technological solutions presented in the form of the sections of Healthcare System Preparation for Health Emergencies (Section I) and Critical Illnesses and Conditions for SUS (Section II), which meet at least one of the criteria defined in articles 6 and 7 of Annex CVII of Consolidated Ordinance #5, of September 28, 2017.

Paragraph 1. Productive and technological solutions comprise productive and technological platforms and products to meet public policies, actions, measures, mechanisms, initiatives, and national programs for the promotion, prevention, diagnosis, treatment, and rehabilitation of health, aiming to overcome the challenges cited in the head provision, and must be environmentally sustainable.

Paragraph 2. For the purposes of Article 75 of Statute #14,133, of April 1, 2021, the products listed within Matrix mentioned in the head provision of Article 2, set out in Annex I, as well as those listed in Annex II, are considered strategic for SUS.

Article 3. This Ordinance has as annexes the Matrix of Productive and Technological Challenges in Healthcare (Annex I) and the list of products with PDPs in force which have been signed with the Ministry of Health in previous years (Annex II).

Article 4. Matrix may be updated by specific acts of the Minister of Health, after consulting with the Executive Group of the Economic-Industrial Health Complex (Geceis).

Article 5. Matrix and its updates will be published on the website of the Secretariat for Science, Technology, and Innovation and the Economic-Industrial Health Complex of the Ministry of Health.

Article 6. GM/MS' Ordinance #704, of March 8, 2017, is hereby revoked.

Article 7. This Ordinance comes into force on the date of its publication.

ANNEX I

MATRIX OF PRODUCTIVE AND TECHNOLOGICAL CHALLENGES IN HEALTHCARE

SECTION I. PREPARATION OF THE HEALTHCARE SYSTEM FOR HEALTH EMERGENCIES		
Healthcare challenges	Productive and Technological Solutions for SUS	
	Platforms	Products
1. PREPARATION FOR RESPONSE TO HEALTH EMERGENCIES AND PROTECTION FOR VACCINE-PREVENTABLE DISEASES	Production platform for scale-up and final processing of bioproducts on a large scale Platform of viral and bacterial technologies for new vaccine production processes	<ul style="list-style-type: none"> – PNI vaccines which require technological updating – PNI vaccines having external dependence – Respiratory syncytial virus (RSV) vaccine – Chikungunya vaccine
		<ul style="list-style-type: none"> 1.– Dengue vaccine – Schistosomiasis vaccine – Leprosy Vaccine – Leishmaniasis vaccine
		<ul style="list-style-type: none"> 1.– Zika Vaccine – Herpes Zoster vaccine – Combination vaccines – Vaccine associated with non-invasive pharmaceutical forms
	1. Platform for RNA-based products and other genetic-based technologies Platform for producing vaccines associated with innovative delivery systems	
	Productive platform for rapid diagnostic testing Productive platform for point-of-care diagnostic testing Productive platform for molecular diagnostic tests Productive platform for in vitro diagnostic testing Medical device production platform	<ul style="list-style-type: none"> – Molecular diagnostic tests, immunoassay, rapid antigen or antibody tests, point-of-care, self-test and other in vitro diagnostic tests – Nucleic acid extraction kit – Syringes and hypodermic needles
2. MODERNIZATION OF PRODUCTIVE TECHNOLOGIES OF IMMUNOPROTECTIVE SERUMS	Productive platform for immunoprotective serums Platform for new biotechnological processes for the production of immunoprotective serums	<ul style="list-style-type: none"> – Immunoprotective serums
3. OVERCOMING VULNERABILITY IN BLOOD DERIVATIVES, BIOPRODUCTS, AND MODERNIZATION OF TECHNOLOGICAL SERVICES IN HEMOTHERAPY	Production platform for blood products and bioproducts Production platform for genetic-based inputs and products Productive platform for advanced therapies	<ul style="list-style-type: none"> – Blood products and bioproducts – New technologies for hemotherapy – Technological services for hemotherapy
	Information technology and connectivity platform for the management of blood centers	<ul style="list-style-type: none"> – Development and local production of information and connectivity technologies for centralization and standardization of serological assays for screening donated blood
	Productive platform for molecular diagnostic tests Production platform for medical devices	<ul style="list-style-type: none"> – State-of-the-art nucleic acid amplification test – Technologies for inactivating pathogens in voluntary donation blood bags – Apheresis machine

SECTION I. PREPARATION OF THE HEALTHCARE SYSTEM FOR HEALTH EMERGENCIES

Healthcare challenges	Productive and Technological Solutions for SUS	
	Platforms	Products
4. TECHNOLOGICAL AND ECONOMIC VULNERABILITY FOR HEALTHCARE ACCESS	<ul style="list-style-type: none"> Production platform for active pharmaceutical ingredients Production platform for nuclear medicine inputs and products Production platform for antimicrobial inputs and products 	<ul style="list-style-type: none"> – Chemical or biotechnological-based APIs for medicines required by SUS which are externally dependent on critical inputs from the production chain for all the healthcare challenges defined in this matrix – Radiopharmaceuticals and nuclear medicine products
		<ul style="list-style-type: none"> – Antimicrobial APIs – Antimicrobial products required by SUS which are not nationally produced and are for resistant microorganisms
	Production platform for medical devices	– Critical inputs for the medical device production chain
5. TECHNOLOGICAL ALTERNATIVES FOR SUSTAINABLE DEVELOPMENT AND GREEN CHEMISTRY	<ul style="list-style-type: none"> Technological and productive routes for active pharmaceutical ingredients based on green chemistry Production platform for biodiversity inputs and products 	<ul style="list-style-type: none"> – APIs obtained by sustainable technological and industrial processes based on green chemistry – Phytotherapeutics and biodiversity products supported by SUS
6. TECHNOLOGIES FOR HEALTHCARE SYSTEMS (SUS)	<ul style="list-style-type: none"> Productive platform for software and applications Productive platform for artificial intelligence Productive platform for the internet of things Productive platform for digital systems 	<ul style="list-style-type: none"> – Development and local production of technologies used in healthcare (remote healthcare, telemonitoring, tediagnosis, among others) – Development and local production of information and connectivity technologies for inventory management
		<ul style="list-style-type: none"> – Development and local production of information and connectivity technologies for traceability of orthoses, prostheses and mobility aids provided by SUS – Development and local production of information and connectivity technologies for the management of clinical data from electronic medical records
		<ul style="list-style-type: none"> – Development and local production of information and connectivity technologies with standards and interoperability at different SUS levels – Development and local production of information and connectivity technologies to monitor the acquisition, dispensing, and shortage of medicines
	<ul style="list-style-type: none"> Production platform for medical devices Production platform for imaging diagnostic equipment Productive platform for wearable devices for rehabilitation and assistive technologies 	<ul style="list-style-type: none"> – Medical equipment adapted for use in primary care, pre-hospital, and home care – Portable medical and dental equipment with alternative energy sources for use in remote locations without infrastructure
		<ul style="list-style-type: none"> – Imaging diagnostic equipment equipped with integrated solutions – Equipment for diagnosis and clinical and surgical therapy for ophthalmology – Assistive technology devices that help and increase the autonomy of people with visual, hearing and motor disabilities

SECTION I. PREPARATION OF THE HEALTHCARE SYSTEM FOR HEALTH EMERGENCIES

Healthcare challenges	Productive and Technological Solutions for SUS	
	Platforms	Products
		– High viscosity glass ionomer cement
	Production platform for OPME and processing of healthcare products Production platform for biomaterials Platform for xenotransplantation-based products	
		– Surgical shoulder, hip, femur, knee, skull, and dental prostheses, in titanium, porcelain, or biomaterials – Ventricular assist device, organ perfusion machines, and extracorporeal membrane oxygenation – Liquid for organ and cornea preservation

SECTION II. CRITICAL DISEASES AND INJURY FOR SUS

Healthcare challenges	Productive and Technological Solutions for SUS	
	Platforms	Products
7. NEGLECTED POPULATIONS AND DISEASES	Production platform for chemical-based inputs and products Production platform for biotechnology-based inputs and products Platform for production of products associated with innovative release systems	– Neglected medicines and New therapeutic schemes to optimize the treatment of Tuberculosis, Chagas Disease, Leprosy, Schistosomiasis, Leishmaniasis, Malaria, and other diseases listed by CIEDDS
	Platform for the production of antiretroviral and viral inputs and products	
		– Medications and new therapeutic regimens required by SUS for the treatment of HIV/AIDS and viral hepatitis – Medicines and formulations for treatment of the pediatric population – Products and nutraceuticals for pediatric or vulnerable populations
	Production platform for antimicrobial inputs and products Industrial pharmaceutical development platform for pediatric formulations Production platform for nutraceuticals	
	Productive platform for rapid diagnostic testing Productive platform for point-of-care diagnostic testing Productive platform for molecular diagnostic tests Productive platform for in vitro diagnostic testing	– RT-PCR platform for diagnosing arboviruses, multiplex, or isolated – Molecular diagnostic tests, immunoassay, rapid antigen or antibody tests, point-of-care, self-test, and other in vitro diagnostic tests – Test to determine sensitivity to antimicrobials – Nucleic acid extraction kit
8. CANCERS WITH HIGHER INCIDENCE Non-melanoma skin cancer,	Production platform for chemical-based inputs and products	– Tyrosine kinase inhibitors – Cyclin inhibitors – Goserelin acetate – Pertuzumab

SECTION II. CRITICAL DISEASES AND INJURY FOR SUS

Healthcare challenges	Productive and Technological Solutions for SUS	
	Platforms	Products
Breast cancer; prostate cancer; colorectal cancer; lung cancer, trachea and bronchi cancer; cervix cancer; thyroid cancer; lymphomas; leukemias PEDIATRIC CANCERS	Production platform for biotechnology-based inputs and products Platform for RNA-based products and other gene-based technologies	
		<ul style="list-style-type: none"> – Trastuzumab deruxtecan – Pembrolizumab – Blinatumomab
	Platform for production of products associated with innovative release systems	
		<ul style="list-style-type: none"> – Lenalidomide – Vesical BCG – L-asparaginase/Pegaspargase – Gene Therapy Products – Products and formulations for treatment of the pediatric population
	Productive platform for advanced therapies Industrial pharmaceutical development platform for pediatric formulations	
	Productive platform for in vitro diagnostic testing Productive platform for medical devices for telemedicine	<ul style="list-style-type: none"> – Equipment and platforms for telecolposcopy, telepathology, and teleradiology – Self-collection kit for HPV detection by molecular biology – Point-of-care testing for cervical cancer – Molecular diagnostic and pathological anatomy tests
9. CARDIOVASCULAR DISEASES	Production platform for chemical-based inputs and products	– Medicines and API used by SUS that are externally dependent on critical inputs from the production chain
	Productive platform for implantable medical devices Productive platform for in vitro diagnostic testing	<ul style="list-style-type: none"> – Platen spiral – Prostheses and other cardiovascular implantable medical devices – Diagnostic tests for measuring and evaluating cardiac markers
10. DIABETES	Production platform for chemical-based inputs and products Production platform for biotechnology-based inputs and products	<ul style="list-style-type: none"> – Medicines and API used by SUS that are externally dependent on critical inputs from the production chain – Insulins and analogues thereof
	Productive platform for artificial intelligence	– Development and local production of information and connectivity technologies for diabetes monitoring
	Productive platform for in vitro diagnostic testing Production platform for medical devices and biomaterials	<ul style="list-style-type: none"> – In vitro diagnostic tests – Medical devices for the treatment of diabetic foot ulcers
11. DISEASES ASSOCIATED WITH POPULATION AGING	Production platform for chemical-based inputs and products	– Medicines and API used by SUS for diseases related to aging that present external

SECTION II. CRITICAL DISEASES AND INJURY FOR SUS		
Healthcare challenges	Productive and Technological Solutions for SUS	
	Platforms	Products
	Production platform for biotechnology-based inputs and products Platform for producing products associated with innovative release systems Productive platform for advanced therapies	dependence on critical inputs from the production chain
	Production platform for medical devices	– Set of electrodes and generator for deep brain electrical stimulation
	Information technology and connectivity platform	– Development and local production of information and connectivity technologies to improve the quality of life of the elderly population
12. RARE DISEASES	Production platform for chemical-based inputs and products Production platform for biotechnology-based inputs and products Platform for RNA-based products and other gene-based technologies	– Products for the treatment of Cystic Fibrosis: ivacaftor / elexacaftor, tezacaftor, and ivacaftor – Products for the treatment of Spinal Cord Atrophy: Risdiplam
		– Selective immunosuppressants for Multiple Sclerosis and Paroxysmal Nocturnal Hemoglobinuria – Enzymes for the treatment of Mucopolysaridosis, Gaucher Disease, Pompe Disease, and Cystic Fibrosis
	Platform for production of products associated with innovative release systems	
		– Products for the treatment of Familial Amyloidotic Polyneuropathy – Products for the treatment of Acromegaly, Rickets, and osteomalacia – Gene Therapy Products – Products and nutraceuticals for patients with inborn errors of metabolism or other rare diseases
	Productive platform for advanced therapies Production platform for nutraceuticals	
	Productive platform for genetic testing	– Equipment and supplies for tracking and confirmatory tests of diseases eligible for neonatal screening – Whole exome sequencing
13. OTHER CHRONIC NON-COMMUNICABLE DISEASES	Production platform for chemical-based inputs and products Production platform for biotechnology-based inputs and products Platform for production of products associated with innovative release systems Productive platform for advanced therapies	– Medicines and API used by SUS for autoimmune, respiratory, and mental disorders that present external dependence on critical inputs from the production chain – Gene Therapy Products

SECTION II. CRITICAL DISEASES AND INJURY FOR SUS

Healthcare challenges	Productive and Technological Solutions for SUS	
	Platforms	Products
	Production platform for medical devices Productive platform for single-use medical devices for renal replacement therapy	<ul style="list-style-type: none"> – Pulse generator for vagus nerve stimulation therapy – Equipment and supplies for peritoneal dialysis – Capillaries, catheters and hemodialysis machine – Rapid test and diagnostic kits for pre-eclampsia
	Productive platform for implantable medical devices Production platform for electrical medical equipment Productive platform for in vitro diagnostic testing	

ANNEX II

STRATEGIC PRODUCTS FOR SUS IN THE CURRENT PDPs

The products listed herein are not eligible for new technology transfer projects, except when dealing with technological updates to convergent production platforms.

STRATEGIC PRODUCTS FOR SUS IN THE CURRENT PDPs	
1	Glatiramer Acetate
2	Adalimumab
3	Alphataliglycerase
4	Atazanavir
5	Interferon beta-1a
6	Bevacizumab
7	Cabergoline
8	Capecitabine
9	Certolizumab
10	Clozapine
11	Daclatasvir
12	Darunavir
13	Dolutegravir
14	Entecavir
15	Entricitabine + Tenofovir
16	Erlotinib
17	Etanercept
18	Everolimus
19	Recombinant Factor VIII
20	Fingolimod
21	Galantamine
22	Golimumab
23	Hydroxyurea
24	Infliximab
25	Recombinant Human Insulin (NPH and Regular)
26	Leflunomide
27	Imatinib Mesylate
28	Mycophenolate Sodium
29	Olanzapine
30	Oseltamivir
31	Palivizumab
32	Pramipexole
33	Quetiapine
34	Rifampicin + Isoniazid + Pyrazinamide + Ethambutol (4 in 1 Tuberculostatic)
35	Riluzole
36	Thermostable Ritonavir
37	Rituximab
38	Rivastigmine
39	Sevelamer

STRATEGIC PRODUCTS FOR SUS IN THE CURRENT PDPs	
40	Sildenafil
41	Sofosbuvir
42	Somatropin
43	Tacrolimus
44	Tenofovir
45	Tenofovir + Lamivudine (2 in 1)
46	Tenofovir + Lamivudine + Efavirenz (3 in 1)
47	Teriflunomide
48	Tocilizumab
49	Trastuzumab
50	Dtpa Vaccine (Adsorbed Diphtheria, Tetanus, and Acellular Pertussis Vaccine)
51	Hepatitis A Vaccine
52	HPV Vaccine
53	Tetra Viral Caccine
54	Ziprasidone