

COMMISSION REGULATION (EU) 2022/2294**of 23 November 2022****implementing Regulation (EC) No 1338/2008 of the European Parliament and of the Council as regards statistics on healthcare facilities, healthcare human resources and healthcare utilisation****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work ⁽¹⁾, and in particular Article 9(1) and Annex II, point (d), thereof,

Whereas:

- (1) Regulation (EC) No 1338/2008 sets out the subjects covered in the healthcare domain for which data and metadata are to be provided for the production of European statistics. In particular data and metadata on healthcare facilities, healthcare human resources, healthcare utilisation, individual and collective services, and the reference periods, intervals and time limits for the data provision should be set out by implementing measures.
- (2) Pursuant to Article 6(1) of Regulation (EC) No 1338/2008, in 2015 and 2018, the Commission launched pilot studies that were completed voluntarily by Member States. The Commission also discussed the needs of users of the statistics with Member States. The outcome of those pilot studies and those discussions was that Union-wide data are needed to strengthen the evidence-base on healthcare information, hence benefitting decisions on public health and social policy.
- (3) In accordance with Article 6(2) of Regulation (EC) No 1338/2008, the Commission carried out a cost-benefit analysis, taking into account the benefits of the availability of variables on healthcare facilities, healthcare human resources and healthcare utilisation in relation to the cost of data collection. It follows from that analysis that those variables should be collected to ensure the comparability and availability of Union-wide data.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the European Statistical System Committee, established by Article 7 of Regulation (EC) No 223/2009 of the European Parliament and of the Council ⁽²⁾,

HAS ADOPTED THIS REGULATION:

*Article 1***Scope**

This Regulation lays down rules for the development and production of European statistics in the area of healthcare facilities, healthcare human resources and healthcare utilisation and individual and collective services, as referred to in Annex II, point (d), first, second and third indent, to Regulation (EC) No 1338/2008.

⁽¹⁾ OJ L 354, 31.12.2008, p. 70.

⁽²⁾ Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities (OJ L 87, 31.3.2009, p. 164).

*Article 2***Definitions**

For the purpose of this Regulation, the definitions set out in Annex I shall apply.

*Article 3***Data required**

Member States shall transmit to the Commission (Eurostat) data for the list of variables, the characteristics and breakdowns as set out in Annex II.

*Article 4***Metadata**

Member States shall provide the Commission (Eurostat) with the necessary reference metadata and quality reports, in particular concerning:

- (a) the data sources and their coverage;
- (b) the compilation methods used;
- (c) information on features of national healthcare facilities, healthcare human resources and healthcare utilisation specific to the Member States that deviate from the definitions set out in Annex I and the variables set out in Annex II;
- (d) information on any changes to the statistical concepts mentioned in Annex I and Annex II.

*Article 5***Reference period**

- 1. The reference period shall be the calendar year.
- 2. The first reference year shall be 2021.
- 3. By derogation from paragraph 2, the first reference year for data on health employment, hospital care and surgical procedures referred to in points 1, 6 and 7 of Annex II shall be 2023.

*Article 6***Provision of data and metadata to the Commission (Eurostat)**

- 1. Member States shall provide the data and reference metadata referred to in Articles 3 and 4 respectively to the Commission (Eurostat) on an annual basis within 14 months after the end of the reference year.
- 2. By way of derogation from paragraph 1, Member States shall provide the data and reference metadata on hospital care and surgical procedures referred to in points 6 and 7 of Annex II within 20 months after the end of the reference year.
- 3. Data and reference metadata shall be transmitted to the Commission (Eurostat) using the single entry point or be made available for retrieval by the Commission (Eurostat) by electronic means.

*Article 7***Data sources**

1. The data shall be compiled mainly from administrative records, as referred to in Article 17a of Regulation (EC) No 223/2009 and shall cover the whole Member State.
2. Where administrative records are not available or of insufficient quality or coverage, use of other sources, methods or innovative approaches shall be accepted insofar as they enable the production of data that are comparable and compliant with the requirements laid down by this Regulation.

*Article 8***Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Definitions referred to in Article 2

1	'Practising physicians' means medical doctors who have graduated in medicine from medical faculties or similar institutions and are licensed to practice. Practising physicians provide services for individual patients, families and communities. It also refers to interns and resident physicians who have graduated in medicine from medical faculties or similar institutions and who provide services under supervision of other medical doctors.
2	'Category of practising physicians' means the predominant (main) area of practice of doctors.
3	'General practitioners' means medical doctors who assume responsibility for the provision of continuing and comprehensive medical care to individuals, families and communities.
4	'Other generalist (non-specialist) medical practitioners' means practitioners who do not limit their practice to certain disease categories or methods of treatment. They do not work in an area of specialisation.
5	'Paediatricians' means medical doctors who deal with the development, care and diseases of children.
6	'Obstetricians' means medical doctors who specialise in pregnancy and childbirth. 'Gynaecologists' means medical doctors who specialise in the functions and diseases specific to women and girls, especially those affecting the reproductive system.
7	'Psychiatrists' means medical doctors who specialise in the prevention, diagnosis and treatment of mental illness.
8	'Group of non-surgical specialists' means medical doctors who specialise in the diagnosis and non-surgical treatment of physical disorders and diseases.
9	'Group of surgical specialists' means medical doctors who specialise in the use of surgical techniques to treat disorders and diseases.
10	'Other specialists not elsewhere classified' means physician specialists not covered by definitions 5 to 9.
11	'Medical doctors not further defined' means medical practitioners who cannot be classified in the other categories (definitions 3 to 10).
12	'Practising midwives' means persons who have a recognised qualification in midwifery, have a license to practice and provide services directly to patients. A midwife is a midwifery professional or a midwifery associate professional. Midwifery professionals provide care and advice to women during pregnancy, labour and childbirth and the post-natal period. Midwifery professionals deliver babies working independently or in collaboration with medical doctors, nurses and other healthcare workers and provide advice and assistance to parents in relation to baby care. Midwifery associate professionals deliver or assist doctors or midwifery professionals in the delivery of babies. Midwifery associate professionals provide antenatal and post-natal care and instruct parents in baby care.
13	'Practising nurses' means persons who have a recognised qualification in nursing, have a license to practice and provide services directly to patients. A nurse is a nursing professional or a nursing associate professional. Nursing professionals assume responsibility for the planning and management of the care of patients, including the supervision of other healthcare workers, working autonomously or in teams with medical doctors and others in the practical application of preventive and curative measures. Nursing associate professionals generally work under the supervision of, and in support of implementation of healthcare, treatment and referrals plans established by medical, nursing and other health professionals.

14	'Practising dentists' means persons who have a recognised qualification in dentistry, have a license to practice and provide services for patients. Dentists diagnose and treat diseases, injuries and malformations of the teeth, gums and related oral structures. They restore normal oral function using a broad range of treatments, such as surgery and other specialist techniques, and advice on oral health. It also refers to interns and resident dentists who have graduated in dentistry from the faculties of medicine and dentistry or similar institutions and who provide services under supervision of other dentists.
15	'Practising pharmacists' means persons who have a recognised qualification in pharmacy and have a license to practice. Pharmacists compound and dispense medications following prescriptions issued by physicians, dentists, or other authorized health practitioners. Pharmacists prepare, dispense or sell medicines and drugs for patients and provide advice.
16	'Medical graduates' means persons who have graduated in medicine from medical faculties or similar institutions in the reporting country, i.e., who have completed basic medical education.
17	'Dentistry graduates' means persons who have obtained a recognised qualification in dentistry in the reporting country.
18	'Pharmacy graduates' means persons who have obtained a recognised qualification in pharmacy in the reporting country.
19	'Midwifery graduates' means persons who have obtained a recognised qualification in midwifery in the reporting country.
20	'Nursing graduates' means persons who have obtained a recognised qualification in nursing in the reporting country.
21	'Hospitals' means the licensed establishments that are primarily engaged in providing medical, diagnostic and treatment services that include physician, nursing and other health services to inpatients and the specialised accommodation services required by inpatients and which may also provide day care, outpatient and home healthcare services.
22	'Hospital beds' means those beds which are regularly maintained and staffed and immediately available for the care of admitted patients. Both occupied and unoccupied beds are included in this concept. Excluded are recovery trolleys and beds for same day care (day case care and outpatient care), provisional and temporary beds. Hospital beds can be partitioned by category of care (definitions 23 and 24) and by function (definitions 25-28) of care.
23	'Somatic care' means healthcare relating to the body, as distinguished from psychiatric care.
24	'Psychiatric care' means healthcare concerning the mind, e.g. dealing with mental and behavioural disorders.
25	'Curative care' means the healthcare services during which the principal intent is to relieve symptoms or to reduce the severity of an illness or injury, or to protect against its exacerbation or complication that could threaten life or normal function.
26	'Rehabilitative care' means the services to stabilise, improve or restore impaired body functions and structures, compensate for the absence or loss of body functions and structures, improve activities and participation and prevent impairments, medical complications and risks.
27	'Long-term care (health)' means the range of medical and personal care services that are consumed with the primary goal of alleviating pain and suffering and reducing or managing the deterioration in health status in patients with a degree of long-term dependency.

28	'Hospital beds for somatic care with function not elsewhere classified' means beds in hospitals that are not classified as being for curative care, rehabilitative care or long-term care.
29	'Hospital beds for psychiatric care' means beds in hospitals accommodating patients with mental health problems. Beds for social long-term care shall be excluded.
30	'Residential long-term care facilities' means the establishments that are primarily engaged in providing residential long-term care that combines nursing, supervisory or other types of care as required by the residents, where a significant part of the production process and the care provided is a mix of health and social services with the health services being largely at the level of nursing care in combination with personal care services.
31	'Beds in residential long-term care facilities' means beds in residential long-term care facilities that are available to persons requiring long-term care.
32	'Magnetic resonance imaging (MRI) units' means machines with an imaging technique designed to visualise internal structures of the body using magnetic and electromagnetic fields which induce a resonance effect of hydrogen atoms. The electromagnetic emission created by these atoms is registered and processed by a dedicated computer to produce the images of the body structures.
33	'Computed tomography (CT) scanner', also known as Computerized axial tomography (CAT) scanner, means an x-ray machine which combines many x-ray images with the aid of a computer to generate cross-sectional views and, if needed, three-dimensional images of the internal organs and structures of the body.
34	'Ambulatory care' means the provision of healthcare services directly to outpatients who do not require inpatient services, including both care provided in offices of general medical practitioners and medical specialists and in establishments specialising in the treatment of day cases and in the delivery of home care services.
35	'Immunisation against influenza' means vaccination that protects against infection by influenza viruses.
36	'Breast cancer screening (mammography) programme' means an organised screening programme intended for the early detection of breast cancer using bilateral mammography.
37	'Cervical cancer screening programme' means an organised screening programme intended for the early detection of cervical cancer.
38	'Inpatient' means a patient who receives treatment and/or care in a healthcare facility, who is formally admitted and who requires an overnight stay. 'Inpatient care' means the care of an inpatient.
39	'Outpatient' means a patient who receives medical and ancillary services in a healthcare facility and who is not formally admitted and does not stay overnight. 'Outpatient care' means the care of an outpatient.
40	'Day case' means a patient who receives planned medical and paramedical services delivered in a healthcare facility and who is formally admitted for diagnosis, treatment or other types of healthcare and is discharged on the same day. 'Day care' is the care of a day case.
41	'Hospital inpatient discharge' means the discharge (formal release) of an inpatient from a hospital. Healthy newborns shall be excluded.
42	'Hospital inpatient bed-days' means the days that an inpatient spends in a hospital. Healthy newborns shall be excluded.

43	'Hospital day case discharge' means the discharge of a day case. It is the release of a patient who was formally admitted in a hospital for receiving planned medical and paramedical services, and who was discharged on the same day. Healthy newborns shall be excluded.
44	'Resident' means a usual resident of a geographical area, that is either (i) a person who has lived in his/her place of usual residence for a continuous period of at least 12 months before the reference date; or (ii) a person who arrived in his/her place of usual residence during the 12 months before the reference date with the intention of staying there for at least 1 year. Where the circumstances described in point (i) or (ii) cannot be established, 'usual residence' shall mean the place of legal or registered residence.
45	'Non-resident' means a person who is not a resident of the reporting country.
46	'Surgical procedures' means medical interventions involving an incision with instruments usually performed in an operating theatre and normally involving anaesthesia and/or respiratory assistance. Surgical procedures can be performed either as inpatient cases, day cases or, in certain instances, as outpatient cases.
47	'Cataract surgery' means a surgical procedure to remove the lens of an eye and, in most cases, to replace it with an artificial lens.
48	'Tonsillectomy' means a surgical removal of the tonsils.
49	'Transluminal coronary angioplasty' means a procedure that opens blocked coronary arteries to improve blood flow to the heart muscle.
50	'Coronary artery bypass graft' means a surgical operation where atheromatous blockages in a patient's coronary arteries are bypassed with harvested venous or arterial conduits.
51	'Cholecystectomy' means a surgical procedure to remove the gallbladder.
52	'Repair of inguinal hernia' means a surgical correction of an inguinal hernia. An inguinal hernia is an opening, weakness, or bulge in the lining tissue of the abdominal wall in the groin area between the abdomen and the thigh.
53	'Caesarean section' means a surgical procedure to deliver a baby through incisions in the abdomen and uterus.
54	'Hip replacement' means a surgical procedure to remove damaged sections of a hip joint and to replace them with a prosthesis.
55	'Total knee replacement' means a surgical procedure whereby the diseased knee joint is replaced with a prosthesis.
56	'Partial excision of mammary gland' means surgical removal of some of the breast tissue due to an area of disease such as a mass/lesion, cyst, tumour, or benign or malignant neoplasm.
57	'Total mastectomy' means a surgical removal of an entire breast.

ANNEX II

List of variables, their characteristics and breakdowns, referred to in Article 3

Variables	Characteristics and breakdowns
1. Data on Health Employment	
1.1. Number of practising physicians by age and sex	Headcount at the end of the reference period. Breakdown by age and by sex. Age: less than 35, 35-44, 45-54, 55-64, 65-74, 75 and older.
1.2. Number of practising physicians by category	Headcount at the end of the reference period. Breakdown by category. Categories: general practitioners, other generalist (non-specialist) medical practitioners, paediatricians, obstetricians and gynaecologists, psychiatrists, group of non-surgical specialists, group of surgical specialists, other specialists not elsewhere classified, medical doctors not further defined.
1.3. Number of practising midwives	Headcount at the end of the reference period. Total number.
1.4. Number of practising nurses	Headcount at the end of the reference period. Total number.
1.5. Number of practising dentists	Headcount at the end of the reference period. Total number.
1.6. Number of practising pharmacists	Headcount at the end of the reference period. Total number.
2. Data on Health Graduates	
2.1. Number of medical graduates	Total number during the reference period.
2.2. Number of dentistry graduates	Total number during the reference period.
2.3. Number of pharmacy graduates	Total number during the reference period.
2.4. Number of midwifery graduates	Total number during the reference period.
2.5. Number of nursing graduates	Total number during the reference period.
3. Data on Hospital Beds and Beds in Residential Long-Term Care Facilities	
3.1. Number of hospital beds for somatic care	Average number during the reference period or total number at the end of the reference period. Breakdown by function. Functions: curative care, rehabilitative care, long-term care, function not elsewhere classified.
3.2. Number of hospital beds for psychiatric care	Average number during the reference period or total number at the end of the reference period.
3.3. Number of beds in residential long-term care facilities	Average number during the reference period or total number at the end of the reference period.

4. Data on Devices for Medical Imaging

4.1. Number of MRI units	Total number at the end of the reference period.
4.2. Number of CT scanners	Total number at the end of the reference period.

5. Data on Ambulatory Care

5.1. Immunisation rate of people aged 65 and older against influenza	<p>Number of people aged 65 and over who have been immunised against influenza during the reference period divided by the average annual population aged 65 and over.</p> <p>or</p> <p>Number people aged 65 and over who have been immunised against influenza for the influenza season, defined as July 1 to June 30, which ended in the reference period divided by the population aged 65 and over in the beginning of the reference period.</p>
5.2. Rate of women aged between 50 and 69 screened against breast cancer within a national breast cancer screening (mammography) programme	<p>Rate: number of women aged 50-69 who have been screened against breast cancer within a national breast cancer screening (mammography) programme within 24 months before the end of the reference period (or according to the specific screening frequency recommended in each country) divided by the number of women aged 50-69 eligible for an organised screening programme.</p> <p>If a country does not have such a programme, it will deliver no value with an appropriate flag instead.</p>
5.3. Rate of women aged between 20 and 69 screened against cervical cancer within a national cervical cancer screening programme	<p>Rate: number of women aged 20-69 who have been screened for cervical cancer within a national cervical cancer screening programme within 36 months before the end of the reference period (or according to the specific screening frequency recommended in each country) divided by the number of women aged 20-69 eligible for an organised screening programme.</p> <p>If a country does not have such a programme, it will deliver no value with an appropriate flag instead.</p>

6. Data on Hospital Care

6.1. Number of hospital inpatient discharges	<p>Total number during the reference period. Breakdown by diagnosis, sex, age group and geographical dimension.</p> <p>Mental and behavioural disorders do not need to be broken down by diagnosis and can be delivered as a group.</p> <p>Age groups: less than 1, 1-4, 5-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80-84, 85-89, 90-94, 95 and older</p> <p>Geographical dimension: NUTS2 region of the residence of the discharged patient (for non-residents: country of residence).</p>
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6.2. Number of hospital inpatient bed-days	<p>Total number during the reference period. Breakdown by diagnosis, sex, age group and geographical dimension.</p> <p>Mental and behavioural disorders do not need to be broken down by diagnosis and can be delivered as a group.</p> <p>Age groups: less than 1, 1-4, 5-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80-84, 85-89, 90-94, 95 and older.</p> <p>Geographical dimension: NUTS2 region of the residence of the discharged patient (for non-residents: country of residence).</p>
6.3. Number of hospital day case discharges	<p>Total number during the reference period. Breakdown by diagnosis, sex, age group and geographical dimension.</p> <p>Mental and behavioural disorders do not need to be broken down by diagnosis and can be delivered as a group.</p> <p>Age groups: less than 1, 1-4, 5-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80-84, 85-89, 90-94, 95 and older.</p> <p>Geographical dimension: NUTS2 region of the residence of the discharged patient (for non-residents: country of residence).</p>
6.4. Number of hospital inpatient discharges for patients who have received somatic curative care	Total number during the reference period.
6.5. Number of hospital inpatient bed-days for patients who have received somatic curative care	Total number during the reference period.

7. Data on Surgical Procedures

7.1. Cataract surgery	Total number during the reference period. Breakdown of procedures by inpatient cases, day cases and outpatient cases.
7.2. Tonsillectomy	Total number during the reference period. Breakdown of procedures by inpatient cases, day cases and outpatient cases.
7.3. Transluminal coronary angioplasty	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.4. Coronary artery bypass graft	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.5. Cholecystectomy	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.6. Repair of inguinal hernia	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.

7.7. Caesarean section	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.8. Hip replacement	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.9. Total knee replacement	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.10. Partial excision of mammary gland	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.11. Total mastectomy	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.