Autorità Garante della Concorrenza e del Mercato

UNOFFICIAL COURTESY TRANSLATION – ONLY THE ITALIAN VERSION HAS LEGAL VALUE

THE ITALIAN COMPETITION AND MARKET AUTHORITY

AT ITS MEETING on May 19, 2026;

HAVING HEARD the Rapporteur, Saverio Valentino;

HAVING REGARD TO Article 102 of the Treaty on the Functioning of the European Union (TFEU);

HAVING REGARD TO Council Regulation No. 1/2003 of December 16, 2002;

HAVING REGARD TO Law No. 287 of October 10, 1990;

HAVING REGARD TO Presidential Decree No. 217 of April 30, 1998;

HAVING REGARD TO the complaint received from Sandoz S.p.A. on November 28, 2025, and subsequently supplemented, most recently, on April 13, 2026;

HAVING REGARD TO the documentation on file;

CONSIDERING the following:

I. THE PARTIES

I.1. *The Biogen Group*

1. Biogen Italia S.r.l. ("Biogen IT": C.F. 03663160962) is a company engaged in the research and development, production, and marketing of

pharmaceutical products derived from biotechnology and other advanced technologies. Biogen IT is indirectly controlled, through the companies Biogen International GmbH and Biogen MA Inc., by Biogen Inc. The revenue generated by Biogen IT in Italy, as reported in the latest approved financial statements for the year 2024, amounted to 306.16 million euros.

2. Biogen Inc. (hereinafter, together with its subsidiaries, with which, for antitrust purposes, it constitutes a single economic entity and therefore a single undertaking, "Biogen") is a company incorporated under U.S. law with its registered office in Cambridge, Massachusetts, and is the parent company of the pharmaceutical group of the same name. Biogen is active worldwide in the research, development, and supply of therapies for a range of neurological and neurodegenerative diseases. In particular, Biogen manufactures the biologic drug[1] based on *natalizumab* (hereinafter "NZB") known as Tysabri. Tysabri has been available in Italy since February 14, 2007, and was patent protected until February 9, 2024.

3. Biogen's consolidated global revenue in 2025 was $9.157 billion, of which $4.038 billion came from multiple sclerosis drugs and $1.665 billion from sales of Tysabri[2] .

I.2. *The reporting entity*

4. Sandoz S.p.A. (C.F. 00795170158) is a sole-shareholder company subject to the management and coordination of Sandoz AG and indirectly controlled by Sandoz Group AG (hereinafter collectively referred to as "Sandoz"). Sandoz is active in the marketing of several generic and biosimilar drugs. Specifically, since 2024, Sandoz has been marketing the NZB-based biosimilar drug[3], known as Tyruko, in Italy.

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[1] Biological medicines are defined by the 2001/83/EC, as amended by Directive 2003/63/EC, as *"a product, the active substance of which is a biological substance. A biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterization and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control.*" The European Medicines Agency ("EMA") further specifies that a biological medicinal product is a medicinal product whose active ingredients have a larger and more complex structure than that of non-biological medicinal products and that, precisely because of this greater complexity, a certain degree of variability in the molecules of the same active ingredient may be observed (see Document EMA/837805/2011).

[2] See Biogen Inc., Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2025.

[3] Biosimilar medicines are developed to be highly similar, in terms of quality, safety, and efficacy, to a reference biological medicine no longer protected by a patent (*the* so-called *originator*). Although they

II. THE COMPLAINT AND THE EVIDENCE GATHERED

5. In its complaint of November 28, 2025, last updated on April 13, 2026, Sandoz reported alleged abusive conduct by Biogen following the patent expiration of its biologic drug for the treatment of multiple sclerosis, known as Tysabri. In summary, according to the complainant, following Sandoz's introduction of the drug Tyruko—a biosimilar based on the same active ingredient as Biogen's Tysabri—Biogen engaged in conduct likely to negatively impact Sandoz's ability to effectively compete with the *originator* product. This conduct allegedly consists of hindering market access and development through Biogen's decision to bundle the Stratify *test* (a *test* necessary to assess the risk of developing a specific disease associated with the use of such drugs) with the drug Tysabri, while refusing to make it commercially available to patients not treated with its drug.

II.1. *Multiple Sclerosis*

6. Multiple sclerosis is a chronic, demyelinating, neurodegenerative, immune-mediated inflammatory disease[4] that affects the central nervous system (brain, spinal cord, and optic nerves). In summary, the immune system mistakenly attacks certain components of the central nervous system, mistaking them for foreign agents, triggering an inflammatory process that damages myelin (the sheath that protects and insulates nerve fibers), oligodendrocytes (the cells that produce myelin), as well as the nerve fibers themselves, located beneath the myelin[5]. Damage to the myelin is called demyelination and can lead to lesions or plaques, which develop in various

contain the same biological substance, a biosimilar and the originator may exhibit minor differences attributable to natural biological variability, the complexity of the molecule, and the manufacturing techniques used. However, these differences must be clinically insignificant in terms of safety, quality, and efficacy for the products to be interchangeable in therapeutic use. Marketing authorization ("MA") for biosimilar drugs is contingent upon passing a comparability assessment, based on a direct comparison between the biosimilar and *the originator*, to demonstrate that any differences do not significantly affect safety, quality, and efficacy. At the national level, the Italian Medicines Agency ("AIFA") recognizes biosimilars as interchangeable with their respective *originator* products, both for patients starting treatment for the first time and for those already on therapy.

[4] This term refers to pathological or defensive processes caused by the direct action of the immune system, including antibodies (humoral response) or T lymphocytes (cell-mediated response).

[5] The immune system is composed of immune cells such as lymphocytes and macrophages, which constantly monitor the body to identify dangerous external agents. In the case of multiple sclerosis, some of these cells cross the blood-brain barrier (which separates the blood from the nervous tissue) and attack the myelin of the central nervous system, causing inflammation and tissue damage. When the inflammation subsides, the body may attempt to repair the myelin, but only incompletely and imperfectly. The brain possesses remarkable neural plasticity and can reprogram neural pathways to compensate for damaged areas. However, when the damage also involves nerve fibers, regeneration is not possible.

areas of the central nervous system, particularly in the optic nerves, the brain, and the spinal cord. Over time, these plaques can develop into areas of scarring (sclerosis), from which the disease derives its name.

7. There are several forms of multiple sclerosis depending on the phenotypes of the neurological symptoms:

a) *relapsing-remitting multiple sclerosis* (hereinafter "RRMS") is the most common phenotype, accounting for approximately 85% of initial cases, and is typically diagnosed in young adults between the ages of 20 and 40. RRMS is characterized by alternating episodes of acute relapses and periods of partial or complete remission. Over time, a significant proportion of patients progress to *secondary progressive multiple sclerosis* (hereinafter "SPMS"), with a transition that is often identifiable only retrospectively;

b) *primary progressive multiple sclerosis* (hereinafter "PPMS") is a form of multiple sclerosis characterized by a deterioration of neurological function from the onset of the first symptoms. Patients who progress to this form from the onset of symptoms account for approximately 15% of the total.

8. In essence, despite its chronic nature, multiple sclerosis has a heterogeneous course, both in terms of neurological symptoms and progression over time. The disease can manifest with relapse episodes, varying rates of progression, and variable accumulation of disability, necessitating a personalized therapeutic approach.

9. According to the Multiple Sclerosis Barometer 2025, published by the Italian Multiple Sclerosis Association (hereinafter "AISM")[6] , there are approximately 144,000 cases of multiple sclerosis in Italy, and about 3,650 new cases are diagnosed each year.

II.2. *Medications for the Treatment of Multiple Sclerosis*

II.2.1. Introduction

10. The drug therapies available for multiple sclerosis can be divided into:

a) relapse-suppressing therapies: consisting of steroid medications (corticosteroids), administered for a few days or weeks at the onset of a relapse with the aim of reducing the duration and residual effects of relapses;

b) long-term "disease-modifying" therapies (DMT – *Disease Modifying Treatment*), which serve to alter the course of the disease by reducing the frequency of attacks and counteracting degeneration and the accumulation of

[6] See https://www.aism.it/sites/default/files/2025-11/Barometro_della_Sclerosi_Multipla_2025.pdf.

disability over time.

11. According to data collected by AISM, in 2024, people receiving DMT accounted for 72.4% of those with multiple sclerosis under care[7] . AIFA estimates that national healthcare spending on multiple sclerosis medications in 2024 exceeds 769 million euros, equal to 2.8% of total Italian pharmaceutical spending[8] .

12. DMTs act through immunomodulatory or immunosuppressive mechanisms with the aim of: (i) reducing the frequency of relapses, (ii) limiting the formation of new lesions on MRI, and (iii) slowing the progression of disability. Within these therapies, drugs can be classified by treatment line (first-, second-, and third-line drugs)[9] . In particular, patients with RRMS usually begin treatment with one of the first-line DMTs. Second-line DMTs are generally indicated only for patients who do not respond to first-line treatments or for patients with rapid disease progression[10] . Third-line DMTs are indicated only after a patient has tried one or more second-line treatments and the treatment has failed.

13. According to AIFA[11] , there are various drugs for the treatment of multiple sclerosis belonging to the ATC classes[12] at Level III: L04A – *Immunosuppressants* and L03A – *Cytokines and Immunomodulators*. It should be noted that these classes do not exclusively include drugs for multiple sclerosis, but also various active ingredients used for autoimmune diseases, cancer treatments, etc. Indeed, the third-level ATC classes L03A and L04A and their fourth-level subclasses group all drugs that act on the immune system and therefore include drugs used for diverse diseases linked to immune system malfunctions (e.g., *lupus*, rheumatoid arthritis, drugs to reduce the risk of transplant rejection, multiple sclerosis, etc.).

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[7] See https://www.aism.it/sites/default/files/2025-11/Barometro_della_Sclerosi_Multipla_2025.pdf.

[8] See AIFA, OsMed Report 2024.

[9] See European Commission Decision AT.40588 - *Teva Copaxone*, dated October 31, 2024, paragraph 245 et seq.

[10] If a first-line treatment fails to manage a patient's symptoms, physicians may prescribe a different first-line treatment before moving on to a second-line treatment.

[11] See AIFA, OsMed Report 2024.

[12] In the ATC classification system, drugs are divided into groups based on the organs or systems they act upon and their chemical, pharmacological, and therapeutic properties. The classification is organized into five hierarchical levels. At the first level, drugs are divided into fourteen major anatomical groups and, within these, into major therapeutic groups (Level II). Levels III and IV are chemical/pharmacological/therapeutic subgroups, while the fifth and final level classifies individual active ingredients.
In this case, group L represents "*Antineoplastic and immunomodulating* agents"; group L04 is that of *"Immunosuppressants*," which includes exclusively the third-level class L04A of *"Immunosuppressants*," while group L03 is that of "Immunostimulants," which includes exclusively the third-level class *"Cytokines and Immunomodulators*."

II.2.2. Natalizumab-based drugs

14. Sandoz and Biogen market, among other products, highly effective DMTs—medications containing the active ingredient *natalizumab* (hereinafter "NZB"), ATC class L04AG03 (i.e., monoclonal antibodies indicated for highly active relapsing-remitting multiple sclerosis).

15. The *originator* drug produced by Biogen, called Tysabri[13] , has been available on the Italian market since February 14, 2007, and is classified in reimbursement class H (hospital use only), with consequent use exclusively in hospitals.

16. The biosimilar drug Tyruko[14] by Sandoz has been marketed in Italy since April 2, 2024 (i.e., after the expiration of Tysabri's patent protection in February 2024) and is classified in reimbursement class H.

17. Tysabri and Tyruko are both marketed as a concentrate for solution for infusion (intravenous), at a dosage of 300 mg (hereinafter "mg300"), administered every four weeks. Biogen's Tysabri is also available in a formulation consisting of two syringes of 150 mg each, for a total of 300 mg, administered subcutaneously every four weeks (hereinafter "mg150x2").

18. Treatment with these drugs is indicated as monotherapy DMT in patients with highly active RRMS, particularly in patients: (i) who exhibit high disease activity despite an adequate course of treatment with at least one DMT, or (ii) who have a severe and rapidly progressing form of the disease[15] . In essence, NZB-based drugs are second-line DMTs.

19. Tysabri and Tyruko must be administered exclusively in specialized centers, under the supervision of physicians with experience in the diagnosis and treatment of neurological disorders, in facilities capable of ensuring timely access to magnetic resonance imaging.

20. The following table shows the retail price and *ex-factory* price[16] of Tyruko and Tysabri. Specifically, the Sandoz biosimilar has a selling price

[13] Tysabri is a biologic medicinal product whose active ingredient, NZB, is a humanized recombinant monoclonal antibody against integrin α4, produced using recombinant DNA technology in a murine cell line.
[14] Tyruko is a medicine based on NZB produced using recombinant DNA technology in a Chinese hamster ovary cell line.
[15] Defined as two or more disabling relapses in one year and with one or more lesions visible on brain MRI or with a significant increase in T2 lesion burden compared to a previous, recent MRI.
[16] Pursuant to the Ministerial Decree of August 2, 2019, setting forth *the* "*Criteria and procedures by which the Italian Medicines Agency determines, through negotiation, the prices of medicines reimbursed by the National Health Service*," negotiations are to take place between AIFA and pharmaceutical companies regarding the reimbursement status of the medicine as well as the price to be borne by the health service (Class A and H medicines). Furthermore, Article 1, paragraph 40, of Law No. 662/1996 stipulates that for Class H drugs, the share attributable to pharmaceutical companies is 66.65% of the retail price (excluding VAT) for the purpose of calculating the *ex-factory* price.

20% lower than that of its *originator*, net of any other discounts.

Table1 – List of NZB-based drugs[17]

Group Description	Name and Packaging	Retail Price	Price *ex-factory*	AIC Holder	Code AIC
Natalizumab 300 mg 15 ml 1 unit for parenteral use	TYSABRI*1 vial for intravenous use, 300 mg, 15 ml	2,681.09	1,624.50	Biogen Netherlands B.V.	037150012
Natalizumab 150 mg 1 ml 2 units for parenteral use	TYSABRI*2 pre-filled syringes SC 1 ml 150 mg/ml	2,681.09	1624.50	Biogen Netherlands B.V.	037150024
Natalizumab 300 mg 15 ml 1 unit for parenteral use	TYRUKO*1 vial IV 300 mg 15 ml 20 mg/ml	2144.87	1299.60	Sandoz GmbH	050762018

21. This price may be subject to further reduction in the case of public tenders. On this point, according to AIFA data, for the period January–September 2025[18] the average price for a package of NZB is 956.9 for Sandoz's biosimilar Tyruko and 1,200.83 for Biogen's *originator* drug Tysabri.

22. The following Table2 shows sales of NZB-based drugs in Italy for the years 2022–2024 and for the first nine months of 2025. Specifically, following its market entry in 2024, Sandoz's biosimilar achieved a sales share of approximately 20–25% between January and September 2025.

Table2 – Sales of NZB-based drugs in Italy (value, 2022–2025)[19]

	2022		2023		2024		Jan-Sept 2025	
	€ million	%	€ million	%	€ million	%	€ million	%
Biogen	136.2	100%	142.6	100%	117.4	90–95%	64.3	75–80%
Sandoz	0.0	0%	0.0	0%	10–30	5–10%	10–30	20–25%
Total	*136.2*	*100%*	*142.6*	*100%*	*120–150*	*100%*	*70–100*	*100%*

II.2.3. The Need for JCV Testing in Patients Receiving Natalizumab

23. Prior to and periodically during treatment with NZB, patients must undergo laboratory *testing* to assess the risk of developing *progressive multifocal leukoencephalopathy* (hereinafter "PML").

24. PML is a severe demyelinating disease of the central nervous system caused by the reactivation of the John Cunningham virus (hereinafter "JCV"

[17] See AIFA, List of Class H Drugs by Active Ingredient (updated as of August 31, 2025; see Doc. 6.5).
[18] See AIFA, Analysis of Regional Variability (September 2025), p. 99 et seq. https://www.aifa.gov.it/documents/20142/3423405/2_Istogrammi_biologico_biosimilare_set-2025.pdf.
[19] See doc. 4.3. The data were provided in USD; for conversion to euros, an exchange rate of 1.1798 dollars per 1 euro was used, see Bank of Italy, Reference exchange rates of February 5, 2026.

or “JC virus”), a polyomavirus that is generally latent in the adult population. It develops primarily in conditions of immune system compromise[20] .

25. Anti-JCV *tests* are serological tests designed to detect the presence of antibodies against the JCV virus in the patient’s serum or plasma, allowing for the determination of current or past exposure to the virus, and serve as a tool for assessing an individual’s risk of developing PML.

26. The use of anti-JCV *tests* is not limited exclusively to multiple sclerosis, as these *tests* are designed to detect the presence of the JC virus and, consequently, to assess the risk of PML in immunocompromised patients across various clinical settings[21] .

27. However, the anti-JCV *test* has gained particularly well-established clinical relevance in the context of multiple sclerosis treatment with NZB, as numerous studies have demonstrated a significant correlation between the anti-JCV antibody titer, the duration of treatment with NZB, any prior use of immunosuppressants, and the risk of developing PML.

28. For this very reason, the Summary of Product Characteristics (SmPC) and the risk management plan document for Tysabri and Tyruko explicitly refer to the risk of developing PML and recommend *testing* prior to the start of therapy, as well as repeating the *test* every six months in patients who are negative for anti-JCV antibodies. Even for patients with a positive but low anti-JCV titer, semi-annual retesting is recommended for up to two years after the start of treatment, beyond which the risk of PML is increased. Therefore, patients treated or to be treated with NZB necessarily undergo these *tests* one or more times.

29. Biogen has developed an anti-JCV *test*, called Stratify, in collaboration with Quest Diagnostics. Stratify is offered through *partner* laboratories in the

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[20] PML was originally described in patients with HIV/AIDS, but has subsequently been observed in contexts unrelated to HIV infection, such as in patients undergoing bone marrow or solid organ transplants, patients with solid tumors, systemic inflammatory diseases, or other conditions associated with immunosuppression. In recent decades, cases of PML have also been reported in patients with multiple sclerosis treated with biologic therapies that modulate or suppress the immune system, particularly with the administration of NZB-based drugs.

[21] For example, the patent for Biogen’s anti-JCV *test*, called Stratify, explicitly states that *“the assay can be used for the detection of JCV antibodies in any human Subject, including a Subject considering treat ment with an immunomodulator, for example an anti-VLA-4 therapy (e.g., natalizumab), an anti-CD20 therapy (e.g., rituximab), an anti-CD11atherapy (e.g., efalizumab), or mycophenolate mofetil, in a Subject currently being treated with an immunomodulator; or a subject that has ceased treatment with an immunomodulator. The assay may be useful to others who may be susceptible to PML, such as individuals having lymphoproliferative disorders, such as multiple myeloma or a lymphoma; individuals infected with human immunodeficiency virus (HIV), or having acquired immune deficiency syndrome (AIDS), hematologic malignancies, or an autoimmune disease Such as systemic lupus erythematosus (SLE), an inflammatory bowel disease. Such as Crohn's Disease (CD) or ulcerative colitis, multiple sclerosis (MS) or arthritis, e.g., rheumatoid arthritis (RA). The assay may also be useful to Subjects receiving immunosuppressive or immunomodulatory therapies, such as transplant patients.*” (see doc. 10.29).

Unilabs network. The Stratify *test* enables the qualitative detection of anti-JCV antibodies. The *testing* service is fully funded by Biogen for patients who are considering or are currently being treated with Tysabri. This *test* is protected by patents until 2032.

30. Sandoz, as part of a collaboration between Polpharma Biologics and GenBio Inc., has developed an anti-JCV *test* called ImmunoWell. This is an in vitro diagnostic *test* for the detection of anti-JCV antibodies. The *test* is offered through a centralized diagnostic service in the European Union.

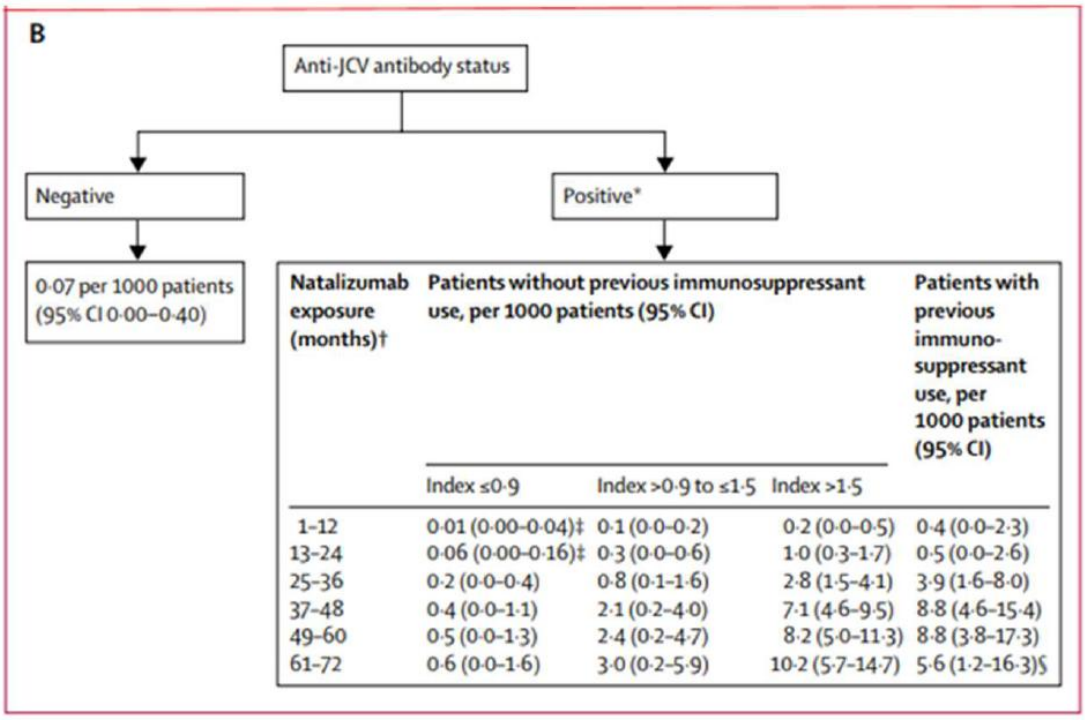
31. Until May 2022, when Sandoz's ImmunoWell *test* received CE marking, Biogen's Stratify appears to have been the only anti-JCV *test* available.

32. Both *tests* are ELISA-based[22] and are designed to return an index value calculated based on the detected optical density. Specifically, both the Stratify and Immunowell tests allow for the quantification of anti-JCV antibodies present in the body. In particular, the *tests* determine the so-called JCV Index, which represents the quantity of antibodies in the patient's serum sample.

33. With specific reference to patients treated with NZB, this index is used as a tool to support the stratification of the risk of developing PML. Essentially, a probability table has been developed (Figure1) which, by considering the JCV Index value, prior use of immunosuppressants, and the duration of NZB therapy, provides an indication of the probability of developing PML and, consequently, whether or not to continue NZB therapy.

[22] *The* ELISA (*Enzyme-Linked Immunosorbent Assay*) *test* is a versatile, highly sensitive immunological diagnostic technique used to detect and quantify substances such as antibodies, antigens, proteins, and hormones in biological samples (blood, serum). Based on specific antigen-antibody binding, it uses an enzyme linked to an antibody to produce a colorimetric signal proportional to the concentration of the target substance.

Figure1 – Probability table for the development of PML based on the JCV Index[23]



Natalizumab exposure (months)†	Patients without previous immunosuppressant use, per 1000 patients (95% CI)			Patients with previous immunosuppressant use, per 1000 patients (95% CI)
	Index ≤0·9	Index >0·9 to ≤1·5	Index >1·5	
1–12	0·01 (0·00–0·04)‡	0·1 (0·0–0·2)	0·2 (0·0–0·5)	0·4 (0·0–2·3)
13–24	0·06 (0·00–0·16)‡	0·3 (0·0–0·6)	1·0 (0·3–1·7)	0·5 (0·0–2·6)
25–36	0·2 (0·0–0·4)	0·8 (0·1–1·6)	2·8 (1·5–4·1)	3·9 (1·6–8·0)
37–48	0·4 (0·0–1·1)	2·1 (0·2–4·0)	7·1 (4·6–9·5)	8·8 (4·6–15·4)
49–60	0·5 (0·0–1·3)	2·4 (0·2–4·7)	8·2 (5·0–11·3)	8·8 (3·8–17·3)
61–72	0·6 (0·0–1·6)	3·0 (0·2–5·9)	10·2 (5·7–14·7)	5·6 (1·2–16·3)§

34. This probability table was developed based on data collected exclusively from patients treated with Tysabri (as it is the *originator* drug) and who underwent the Biogen Stratify *test* (thus referring to the Stratify JCV Index). Specifically, the probability table for PML risk with NZB was constructed by analyzing 37,249 patients, followed *for* up to fifteen years, using data from four large observational studies.

35. Despite this specificity of the probability table, both *tests* have been authorized to assess the immune response to the JCV virus in relation to the use of the active substance NZB, regardless of the specific NZB-based drug prescribed for the patient's treatment.

36. On this point, it should be noted that—although the ImmunoWell *test* has been clinically validated through direct comparison with Biogen's anti-JCV *test* and was deemed accurate in validation studies and in the EMA's approval document—the two *tests*, due to methodological differences, yield different estimates of the JCV Index. In this regard, the EMA has indicated that the two *tests* have a high level of agreement, but the ImmunoWell *test* may underestimate the JCV Index compared to the Stratify *test* estimator[24] . It

[23] See doc. 10.1.

[24] See doc. 4.14. *"High concordance was found for assay sensitivity and NPV, whereas PPV had only 67% performance in MS patients. Since the assay is intended to reliably detect anti-JVC antibodies in patients, the values for sensitivity and NPV are the most critical, whereas a low PPV does not raise concerns about missing JVC infections in patients. However, in clinical practice, the cut-off values described above for determining*

is important to highlight that the scientific literature has found that patients with JCV Index values near the negative/positive threshold tend to be classified as negative by one *test* and positive by another (and vice versa)[25] .

37. Therefore, in consultation with the EMA, it was decided to slightly adjust the class intervals within which a given antibody titer falls (the EMA's public assessment report on Tyruko mentions the values of 0.9 and 1.5 for Stratify (used in the probability table atFigure1 *supra*) and 0.8 and 1.4 for ImmunoWell[26] .

38. In this context, therefore, although the ImmunoWell *test* can be used to support the assessment of PML risk (using the same probability table developed for the Stratify *test*) in patients treated with NZB, these discrepancies give rise to some clinical uncertainties regarding the assessment of the risk of developing PML due to the aforementioned inconsistency.

39. Furthermore, it should be noted that the probability table based on Stratify's JCV Index was developed by conducting the Stratify *test* on a large number of patients (37,249) who were treated with Biogen's Tysabri, with *a follow-up* period of fifteen years, that is, over a timeframe during which Stratify and Tysabri were, respectively, the only anti-JCV assay and the only NBZ-based drug available on the market.

40. Consequently, in the absence of a critical mass of patients and a long follow-up period, it does not appear possible to statistically reconstruct equivalent Kaplan-Meier curves, *life tables*, or *hazard ratios*. PML is, in fact,

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positive/negative results are of relatively minor importance. Rather, risk stratification is currently based on index values between 0.9 and 1.5 in clinical practice. Therefore, the applicant presented further comparative test data from the healthy subject population across the entire index range, and based on a regression analysis, it was suggested that the ImmunoWELL JCV IgG test might slightly underestimate the index estimated from the STRATIFY JCV DxSelect test (see also Discussion on clinical safety). […] *At the relevant threshold values of 0.9 and 1.5, the estimated ImmunoWELL JCV IgG test values for MS patients are 0.882 (90% confidence interval: 0.849–0.921) and 1.451 (90% confidence interval: 1.388–1.517). The relative differences are 2.0% and 3.3%, respectively. If a minor offset exists between the two assays, it is expected to be below 0.1 index values*."

[25] Specifically, a 2025 study of 250 patients found that 47.9% of patients who had previously tested negative with Stratify tested positive with ImmunoWell (see doc. 10.25); in a study conducted between 2024 and 2025 involving 113 patients who were administered both *tests* simultaneously, 27 (24%) tested positive on one *test* and negative on the other (see doc. 10.26); finally, in a further 2025 study of 120 patients who underwent both *tests* simultaneously, the tests showed a 94.2% agreement rate, with discordance concentrated in cases where the JCV Index values were close to the threshold between positive and negative (see doc. 10.27).

[26] See doc. 4.14. *"For both the combined MS patient populations and the healthy subject population, high sensitivities were observed at the threshold values of 0.9 (92.1% and 94.3%) and 1.5 (89.7% and 91.3%), corresponding to low numbers of false negatives. Additionally, the specificity values in this analysis indicate strong agreement, with results of 91.9% and above. The revised threshold values of 0.8 and 1.4 generally lead to a minor improvement in sensitivity for the ImmunoWELL JCV IgG test (e.g., from 92.1% to 92.9% at the lower threshold and from 89.7% to 91.4% at the upper threshold for MS patients) and a concomitant minor reduction in specificity (see Discussion on Clinical Safety)*.".

extremely rare[27] , and, furthermore, the clinical safety measures subsequently adopted for patients treated with NBZ entail discontinuation of therapy in the event of a PML risk, making it even more difficult to develop a new probability table for the risk of developing this fatal disease.

41. In essence, the Stratify *test* appears to constitute a statistical *standard* upon which risk stratification in NZB-based treatment is based. This means that the medical community prefers to rely on *the* Stratify *test* as a benchmark for assessing the risk of developing PML in patients receiving NZB, based on the probability table that correlates Stratify's JCV Index values, duration of therapy, and actual cases of PML.

II.3. *The reported conduct*

42. Following the expiration of Biogen's Tysabri patent, Sandoz introduced the drug Tyruko in Italy, a biosimilar based on the same active ingredient as Tysabri. According to the complainant, Biogen then engaged in conduct likely to negatively impact the Company's ability to effectively compete with the *originator* product.

43. In particular, as noted above, patients with multiple sclerosis who are prescribed NZB must undergo specific anti-JCV laboratory *tests* before starting treatment and periodically throughout the course of treatment. Specifically, these are the Stratify and ImmunoWell *tests*; the former, for the reasons previously outlined, appears to be the standard of care among the medical community.

44. However, according to the complainant, Biogen's Stratify *test* is made available in a manner that restricts its use solely to the administration of the drug Tysabri, thereby eliminating the possibility of using the same *test* in conjunction with the competing product, namely Sandoz's Tyruko.

45. Following the acquisition of further information, it emerged, first of all, that Biogen had filed several divisional patents that were subsequently invalidated: in fact, prior to the expiration of the NZB patent in February 2024, Biogen filed several divisional patent applications with the *European Patent Office* (EPO)[28] relating to the Stratify anti-JCV antibody test, aimed at linking the assay to the specific application of PML risk stratification in patients

[27] In the study on which the Stratify probability table was developed, only 156 cases out of over 37,000 patients, approximately 0.4%, developed PML.

[28] Divisional patents are secondary patent applications derived from a "parent" patent. While sharing the same filing date and disclosure content, divisional patents allow for the filing of new claims relating to different aspects of the invention.

receiving NZB; many of these have been invalidated, while the remaining ones are still under review[29] .

46. Second, it has emerged that Biogen refuses to provide the *testing* service if patients are not being treated with its drug: in fact, the platform made available by Biogen to healthcare facilities for requesting the *test* includes a field asking whether *"Is the patient a candidate for drug therapy with Tysabri?*"[30] and, if the answer is no, the message *"We regret to inform you that the request for the Stratify JCV test for this patient cannot be processed"* appears. *The JCV testing service is fully funded by Biogen for patients who are being evaluated for or have been prescribed TYSABRI. Biogen does not have clinical data on the risk of PML associated with products other than TYSABRI and therefore cannot provide guidance on mitigating the risk of PML with products other than* TYSABRI…"[31] .

47. Furthermore, according to the complainant, Biogen claims to have developed and validated the *test* exclusively for use with Tysabri, thereby excluding its use for patients treated with Tyruko, without any medical or scientific basis. Finally, Biogen reportedly sent Sandoz letters of formal notice on June 28, August 7, and October 2, 2024, contesting that the communication materials regarding the Tyruko product contained passages that conflicted with the terms of use for the Stratify *testing* service, according to which: *"The StratifyJCV Unilabs Service provides the Institution with a digital platform to request the StratifyJCV test, fully funded by Biogen, for patients with multiple sclerosis who are considering or have been prescribed Tysabri (natalizumab-Biogen)*"[32] .

48. Third, although a request to purchase the Stratify *test* from Biogen was made even before the start of the ImmunoWell development phase[33] , which began in 2019, and although Sandoz reiterated this request on several

[29] In particular, the most significant among these are (i) the "2027 Patents" patent family, which pertains to the use of *the* anti-JCV antibody *test* as a decision-making criterion for whether or not to initiate treatment with NZB in patients who test negative for the *test* (patents EP2676967, revoked by the EPO, EP3620469, withdrawn, EP4276469, evaluation still pending); (ii) the "2032 Patents" patent family, which concerns the classification of PML risk as high if the anti-JCV antibody index exceeds the threshold value of 1.5 (patents EP2715352, revoked by the EPO, EP3575792, revoked, EP4187248, rejected by the EPO during examination, EP26154346, pending publication); (iii) the "2034 Patents" patent family, relating to methods for stratifying PML risk based on anti-JCV antibody index values (EP3004334, under examination).

[30] "*Is the patient considered for Tysabri medication?*" (see Doc. 1.1, p. 4).

[31] *"We are sorry to inform you that the Stratify JCV test request for this patient cannot be processed. The JCV testing service is fully funded by Biogen for patients who are considering or have been prescribed TYSABRI. Biogen has no clinical data on the PML risk associated with products other than TYSABRI and therefore cannot provide guidance on PML risk mitigation with products other than TYSABRI* […]". (see doc. 1.1, p. 4).

[32] See Doc. 1, pp. 5 et seq.

[33] See doc. 10.1.

occasions between 2023 and 2025, Biogen reportedly did not follow up on these requests to make the Stratify *test* available in conjunction with Tyruko.

49. According to the complainant, this conduct, taken as a whole, and the resulting unavailability of Biogen's Stratify *test* for patients receiving Sandoz's Tyruko biosimilar would constitute a barrier to market entry, since the majority of the medical community would request the Stratify *test* and, if it could not be used, the supply of Sandoz's drug would be compromised and demand redirected toward Biogen's *originator* drug.

50. On this point, the Complainant also provided evidence regarding the trend in Sandoz's supply of NZB drugs, which appears to confirm the difficulty in competing in the market. In fact, although following the expiration of the Tysabri patent (February 2024) and the start of Tyruko's marketing in Italy, multiple regional tenders have been held for the purchase of off-patent biologics—as shown in the table atTable3 , Sandoz appears to supply only a limited share of these.

Table3 – List of public tenders with a regional or multi-regional scope awarded after Tyruko entered the market[34]

CIG	Contracting Authority	Regional scope	Successful bidder	Valid from	Valid until[35]
A03EF07748	Società Di Committenza Regione Piemonte Spa - SCR Piemonte Spa	Piedmont, Molise, Aosta Valley	Sandoz	03/15/2024	05/31/2026
B16E7662CA	Azienda Zero - Veneto Region	Veneto, Trentino-Alto Adige	Sandoz	05/28/2024	11/30/2027
B1891FCA6C	Aria	Lombardy	Biogen	06/14/2024	08/23/2027
A03027E55E	Areacom Regional Agency of Abruzzo for Public Procurement	Abruzzo	Biogen	06/17/2024	N/A
B0F3F83943	Lazio Region	Lazio	Sandoz	June 19, 2024	12/30/2027
B0CD7CBDD1	Sardinia Region	Sardinia	Sandoz	06/24/2024	06/30/2028
B1D1ACB864	SICILIAN REGION - Regional Department of Economy (CUC)	Sicily	Sandoz	07/02/2024	07/01/2027
B166621594	Ancona Local Health Authority	Marche	Sandoz	07/03/2024	07/31/2029
B205944C48	ESTAR - Regional Technical and Administrative Support Agency	Tuscany	Sandoz	07/19/2024	12/31/2025
B1A2DF748D	Intercenter	Emilia-Romagna	Biogen	08/21/2024	11/30/2027
B255DA6449	Punto Zero S.C.A.R.L.	Umbria	Framework Agreement: 1. Sandoz 2. Biogen	10/25/2024	10/31/2026
B262EB48BB	Innovapuglia Spa	Apulia	Sandoz	12/16/2024	12/31/2028
B40FF86026	Liguria Regional Single Contracting Authority (Suar)	Liguria	Sandoz	12/19/2024	12/31/2026
B61EB240B7	So.Re.Sa. Inc.	Campania	Sandoz	06/01/2025	December 1, 2027
B6BD13B32B	Innovapuglia Spa	Apulia	Sandoz	07/09/2025	07/31/2029
B3B738B214	Single Contracting Authority of the Basilicata Region (Sua-Rb)	Basilicata	Framework Agreement: 1. Sandoz 2. Biogen	July 18, 2025	12/31/2028
B91D1031A5	Arcs Regional Health Coordination Agency	Friuli-Venezia Giulia	Sandoz	10/26/2025	10/25/2027
B7706CEF54	ESTAR - Regional Technical and Administrative Support Agency	Tuscany	Sandoz	10/27/2025	04/26/2030
B8B9308FA8	Calabria Region - Regional Single Contracting Authority (Sua)	Calabria	Sandoz	01/14/2026	07/31/2029

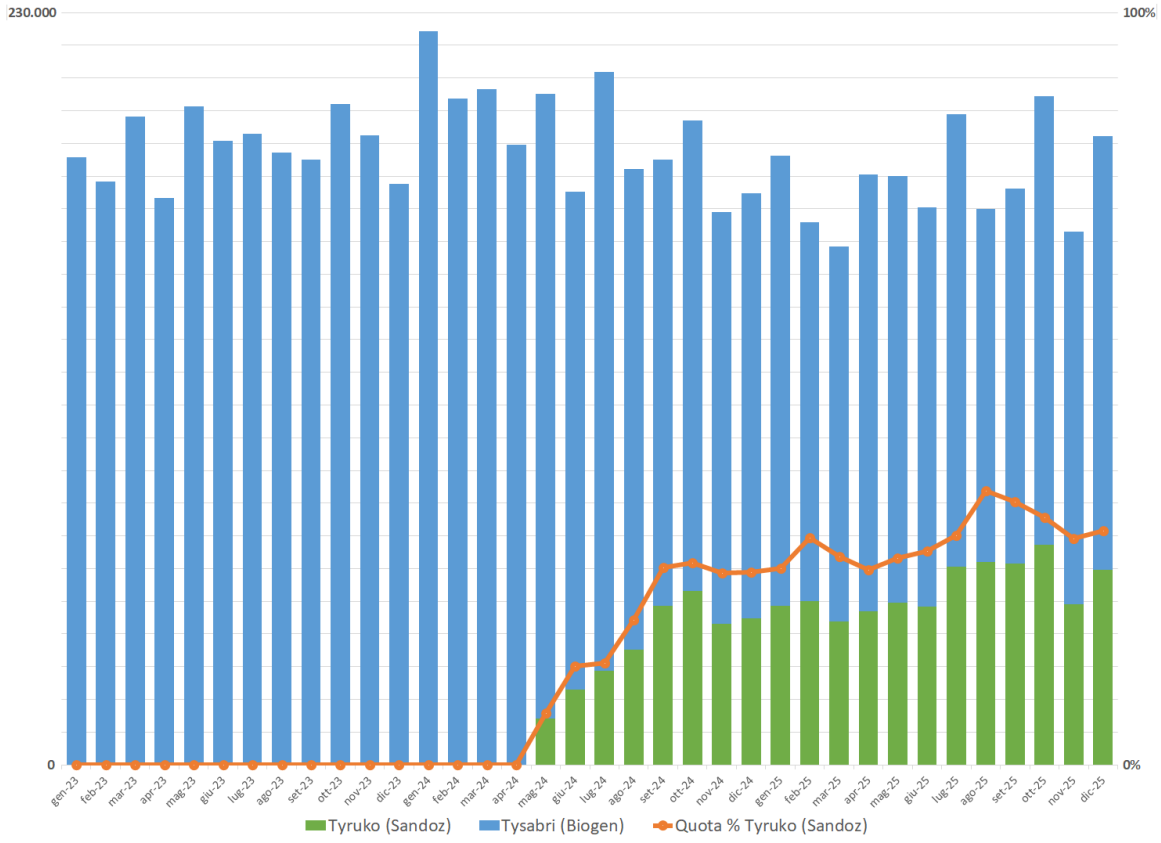
51. Specifically, given a potential demand awarded to Sandoz through a tender resulting from regional aggregation, amounting to approximately 75% of the national demand for NZB (by volume,Table No.4), the share of NZB sales attributable to Sandoz, as of December 2025, is only 30–35% (Figure2 , below).

[34] See analysis in doc. 15.1.
[35] Including any extensions.

Table No.4 – Summary of awards by regional area[36]

Contract Awardee	Regional Areas	Share of NZB demand in the national total (*standard* volumes, 2025)
Sandoz	Calabria, Campania, Friuli-Venezia Giulia, Lazio, Liguria, Marche, Molise, Piedmont, Apulia, Sardinia, Sicily, Tuscany, Trentino-Alto Adige, Valle d'Aosta, Veneto	75%
Framework agreement (Sandoz I awarded the contract)	Basilicata, Umbria	2%
Biogen	Abruzzo, Emilia-Romagna, Lombardy	27%

Figure2 – Sales of NZB-based drugs in Italy (*standard* volumes) and Tyruko's share of sales[37]



52. In summary, although Sandoz's biosimilar drug Tyruko is significantly cheaper than Biogen's originator drug Tysabri, Sandoz's sales volume has consistently been 35–40% lower than expected demand in these regions, which account for approximately 75% of national demand (Figure2).

53. On this point, it should be noted that regulations governing drug supply

[36] See analysis in docs. 15.1 and 15.2.
[37] Analysis in Doc. 15.2.

stipulate that, in the competitive comparison of biosimilar drugs, batches must contain only the specific active ingredient (ATC Level V), the same dosage, and the same route of administration. In any case, the physician is free to prescribe the drug deemed appropriate to ensure therapeutic continuity for patients[38] , although the national recommendation is to use the biosimilar drugs that won the tenders[39], due to the interchangeability between the reference *originator* drug and its biosimilars[40] .

54. The availability of Biogen's Stratify *test* only in combination with the drug Tysabri, from the same company, appears to have hindered the new entrant, favoring instead purchases of the more expensive Tysabri, both in the

[38] In the context of drug procurement, contracting authorities—typically regional purchasing centers—generally use open competitive procedures in accordance with the Public Contracts Code (Legislative Decree No. 36 of March 31, 2023) to ensure effective competition among economic operators. The most common methods include, in particular, the open procedure and the framework agreement. With specific regard to biosimilar medicines, Article 15, paragraph *11-quater*, of Decree-Law No. 95/2012 provides that *"The existence of a biosimilarity relationship between a biosimilar medicine and its reference biologic exists only where established by the European Medicines Agency (EMA) or the Italian Medicines Agency, considering their respective competences. Automatic substitution between a reference biological medicine and its biosimilar, or between biosimilars, is not permitted. In public procurement procedures for biosimilar medicines, different active ingredients may not be included in the same tender lot, even if they have the same therapeutic indications. In order to rationalize spending on the procurement of off-patent biological medicines for which biosimilars are available on the market, the following provisions apply: a) public procurement procedures must be conducted through the use of framework agreements with all economic operators when there are more than three medicines based on the same active ingredient. To this end, regional procurement agencies shall establish a single lot, the composition of which must consider the specific active ingredient (ATC Level V), the same dosage, and route of administration as " " (equivalent); b) in order to ensure effective rationalization of spending while maintaining broad availability of treatments, patients must be treated with one of the top three drugs in the framework agreement ranking, classified according to the criterion of the lowest price or the most economically advantageous offer . The physician is, however, free to prescribe the drug, from among those included in the procedure referred to in subparagraph a), deemed suitable to ensure therapeutic continuity for patients ; c) in the event of the expiration of the patent or supplementary protection certificate for a biologic drug during the term of the supply contract, the contracting authority shall, within sixty days of the market launch of one or more biosimilar drugs containing the same active ingredient, initiate a competitive comparison between these and the reference originator drug in accordance with the provisions of subparagraphs (a) and (b); d) the contracting authority is required to supply the prescribing centers with the products awarded through the procedures set forth in Legislative Decree No. 50 of April 18, 2016* [repealed and replaced by Legislative Decree No. 36 of March 31, 2023]*; e) any additional financial costs arising from failure to comply with the provisions of this paragraph may not be charged to the National Health Service*."

[39] In this regard, see AIFA, 2026, *AIFA's Third Position Paper on Biosimilar Medicines*, in which the Regulatory Authority states that: *"In light of the EMA-HMA statement and the EMA authorization procedure, which guarantees the interchangeability of biosimilars with the reference medicinal product (and vice versa) or with another biosimilar of the same reference product,* […]. *In order to contribute to the sustainability of the National Health Service, it is recommended, in accordance with the principle of loyal cooperation among prescribing physicians, pharmacists, and regions, to promote the informed and efficient use of available resources. In this context, for treatment-naïve patients, prescriptions should be limited to products that have won the regional tender, while for patients already on treatment, it is advisable to consider, where conditions permit, the possibility of switching to the products that have won the tender. If the prescribing physician deems it necessary to opt for different products, it is recommended that the relevant clinical justifications be documented. Finally, it is recommended that the Regions promptly inform prescribing physicians and pharmacists regarding the awarded biologic medicines, including through the digitization of the procedure for updating drug registries* [...]".

[40] See EMA, September 13, 2022, *Interchangeability of biosimilar medicines*, EMA/596658/2022.

300 mg infusion version—which competes in the same tender lot as Sandoz's Tyruko[41] —and in the 150 mg x 2 (for a total of 300 mg, from two subcutaneous syringes), whose sales began well after marketing authorization[42] and inclusion in reimbursement class H[43] and whose procurement methods, due to the different administration method, are excluded from competitive comparison with the competitor as they cannot be included in the same tender lot[44] .

III. ASSESSMENTS

III.1. *The relevant markets and the dominant position*

III.1.1. The market for laboratory diagnostic services for JCV screening

55. JCV *tests* are diagnostic *tests* used to detect the presence of JCV antibodies by collecting a serum sample and sending it to a laboratory for analysis. These are therefore in vitro *diagnostic* (IVD) *tests*[45] .

56. According to the European Commission's decision-making practice[46] , IVD *tests* performed in laboratories have been distinguished from *tests* conducted at the point of care (*point-of-care* – POC IVD)[47] . The European

[41] According to Article 15, paragraph *11-quater*, letter c), of Decree Law No. 95/2012 *"in the event of the expiration of the patent or supplementary protection certificate for a biologic medicinal product during the term of the supply contract, the contracting authority shall, within sixty days of the marketing authorization of one or more biosimilar medicinal products containing the same active ingredient, initiate a competitive comparison between these and the reference originator medicinal product in accordance with the provisions of subparagraphs (a) and (b);*". The procurement procedures, pursuant to Article 15, paragraph *11-quater*, letter d), of Decree Law No. 95/2012, are those provided for by the Public Contracts Code (Legislative Decree No. 36 of March 31, 2023).

[42] See AIFA Resolution No. 92/2021 of June 24, 2021, Official Gazette General Series No. 158 of July 3, 2021 (see doc. 14).

[43] See AIFA Decision No. 477/2023 of July 10, 2023, Official Gazette General Series No. 167 of July 19, 2023 (see Doc. 14).

[44] See Article 15, paragraph *11-quater*, letter a) of Decree Law No. 95/2012. Pursuant to Article 15, paragraph *11-quater*, letter d), of Decree Law No. 95/2012, procurement procedures are those provided for by the Public Contracts Code (Legislative Decree No. 36 of March 31, 2023); therefore, in the presence of a single supplier for the specific administration method of the mg150x2 version, it is, for example, possible to use a negotiated procedure without publication of a call for bids (Article 76 of the Public Contracts Code) or, if the size requirements are met, through direct award (Article 50 of the Public Contracts Code).

[45] See C11444 - *Roche Deutschland Holding/Verum Diagnostica*, Decision No. 23250 of January 25, 2012, in Bulletin No. 4/2012.

[46] See European Commission Decision M.7982 - *Abbott Laboratories/Alere* of January 25, 2017.

[47] See European Commission Decisions M.4569 – *GE/Bott Solvay Diagnostics Division* of April 24, 2007, paragraph 17; M.4788 – *Rozier/BHS* of August 21, 2007, paragraph 12; M.6175 – *Danaher/Beckman Coulter*, June 16, 2011, para. 9; M.6293 – *Thermo Fisher/Phadia*, August 18, 2011, para. 8; M.7787 - *Panasonic Healthcare/Bayer's Diabetes Care Business* of November 23, 2015, paragraph 17; and M.7982 - *Abbot Laboratories/Alere* of January 25, 2017, paragraph 61. Based on the same decision-making practice—which,

Commission has also previously defined the market for the provision of laboratory services for diagnostic purposes, noting that these constitute a market distinct from laboratory services related to clinical development[48] .

57. In the case at hand, it is considered that the market for laboratory diagnostic services for anti-JCV *screening* can be defined. Specifically, this involves the supply of materials and the provision of *testing* services and results to verify the level of anti-JCV antibodies for hospitals.

58. From a geographic perspective, it should be noted that the market appears to be national in scope, due to the national-level specificities of diagnostic *test* procurement and the need for local organization for serum sample collection[49].

59. Currently, the only two *tests* capable of detecting anti-JCV antibodies are Stratify by Biogen and ImmunoWell by Sandoz-Polpharma Biologics. Both tests are offered free of charge and are used on patients receiving NZB.

60. Therefore, the volume of test supplies corresponds to the number of patients treated with Tyruko and Tysabri, and, in essence, Biogen accounts for over 70% of anti-JCV testing in Italy.

III.1.2. Biogen's dominant position in the market for laboratory diagnostic services for anti-JCV screening

61. A dominant position has been defined under EU law as a position of economic strength enjoyed by an undertaking, which enables it to prevent the maintenance of effective competition in a relevant market, giving it the power to behave to an appreciable extent independently of its competitors, its

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however, is developed with a view to the supply of equipment, reagents, and *tests* to laboratories and healthcare facilities—within laboratory IVD *testing*, the European Commission has considered a possible distinction between clinical chemistry, immunochemistry, hematology/histology, microbiology, infectious immunology, and genetic *testing*. Furthermore, the European Commission has, in the past, assessed a possible sub-segmentation within each category by distinguishing thematic *test* panels or examining specific *tests* (see European Commission Decisions M.4321 – *Siemens/Bayer Diagnostics* of October 31, 2006, paragraph 17; M.4569 – *GE/Abbott Diagnostics Division* of April 24, 2007, paragraph 19; M.4865 – *Siemens/Dade Behring* of October 25, 2007, paragraph 23; and M.6293 – *Thermo Fisher/Phadia* of August 18, 2011, paragraph 17).

[48] See European Commission Decision M.10304 – *Thermo Fisher/PPD* of December 7, 2021, paragraph 31.

[49] On this point, see, for example, European Commission Decision M.7982 – *Abbott Laboratories/Alere* of January 25, 2017. In any event, it should be noted that even if a broader geographic market definition were considered, coinciding with the European Economic Area, the conclusions regarding the dominant position would not change. On this point, it should be noted that, according to the European Commission's guidelines on the definition of relevant markets, *"it is not necessary for the Commission to reach a definitive conclusion on the exact scope of the market when the outcome of the Commission's assessment would not change in the presence of various plausible market definitions. The Commission may leave the market definition open both in situations where competition concerns arise regardless of the market definition applied, and where, regardless of the market definition applied, no competition concerns* arise" (see *"Commission Notice on the definition of the relevant market for the purposes of the application of EU competition law (C/2024/1645)*," paragraph 20).

customers, and, ultimately, consumers[50] . Furthermore, according to established case law at both the EU and national levels, the concept of a dominant position includes, among other things, the power of a dominant undertaking in a given market to influence the competitive process even in related markets[51].

62. With regard to the market for laboratory diagnostic services for JCV *screening*, Biogen's Stratify *test* appears to be used in over 70% of cases.

63. According to established EU and national case law, the existence of very high market shares constitutes, in itself and barring exceptional circumstances, evidence of a dominant position. This applies in particular when an undertaking holds a market share of 50% or more[52] , although a dominant position has also been found to exist in cases where an undertaking holds a market share of less than 50%[53].

64. In addition to this factor, it should be noted that, until May 2022, Biogen's Stratify was the only authorized test for *screening* anti-JCV antibodies, and therefore its index values, the JCV Index, appear historically to have served as the benchmark for therapeutic decisions regarding the administration of NZB to patients and the discontinuation of treatment, in order to prevent the development of a potentially fatal disease, PML.

65. Given the historical use of the Stratify test, it appears to have become the *standard* of reference for the probability table of PML development in patients receiving NZB, developed based on more than 15 years of data and the occurrence of PML cases themselves.

66. Furthermore, the development of probability tables alternative to Stratify's is unlikely, at least in the short and medium term, due to: (i) the time required for data *follow-up*; (ii) the limited number of patients receiving the only alternative test (Immunowell by competitor Sandoz); (iii) the fact that safety measures aimed at preventing the development of PML will further limit the ability to collect data on adverse events (the development of potentially fatal PML) and, consequently, the development of the probability

[50] See, *among others*, Council of State, VI, June 5, 2024, No. 5054 - A378E - *Federe - Italy/Fise*.

[51] See Council of State, VI, May 6, 2014, No. 2302, A413 - *TNT Post Italia/Poste Italiane*. See also the judgment of the Court of Justice of the European Union of November 14, 1996, *Tetra Pak v. Commission*, C-333/94 P, ECLI:EU:C:1996:436.

[52] See judgments of the Court of Justice of the European Union of February 13, 1979, *Hoffmann-La Roche & Co. v. Commission*, Case 85/76, ECLI:EU:C:1979:36, para. 41; of July 3, 1991, *Akzo v. Commission*, C-62/86, ECLI:EU:C:1991:286, para. 60. See also Council of State, VI, April 1, 2021, No. 2727, A487 - *Compagnia Italiana di Navigazione-Trasporto Marittimo delle Merci da/per la Sardegna*, as well as the judgment of the General Court of December 12, 1991, *Hilti v. Commission*, T-30/89, ECLI:EU:T:1991:70, para. 92.

[53] See judgment of the Court of Justice of the European Union of February 14, 1978, *United Brands Company and United Brands Continentaal v. Commission*, Case 27/76, ECLI:EU:C:1978:22, paragraphs 108 and 109.

tables themselves.

67. Therefore, in light of these factors, it is considered that Biogen holds a dominant position in the national market for laboratory diagnostic services for anti-JCV *screening*.

III.1.3. The market for natalizumab-based drugs for the treatment of multiple sclerosis

68. With regard to market definition, the established practice of the European Commission and the case law of the Court of Justice of the European Union[54] , consistently applied by the Authority as well[55] , indicates that the identification of the relevant product market in the pharmaceutical sector is based on the concept of therapeutic substitutability of medicines.

69. To analyze this relationship of interchangeability, the starting point is the therapeutic classes identified by the ATC system[56] . However, considerations related to physicians' prescribing trends, the institutional organization of supply and demand for these products, and the greater or lesser efficacy of a drug in treating the condition often require a more specific analysis of substitutability, which may lead to the identification of interchangeability relationships between medicines at a different level of the ATC classification.

70. Moreover, for generic products, which compete primarily on price, the European Commission has defined the relevant product market at the active ingredient level (for example, see the *Novartis/GSK* case[57] and the

[54] See European Commission Decision A. 37.507/F3 – *AstraZeneca* of June 15, 2005, paragraphs 380 et seq. With regard to that case, it is worth noting that both the General Court of the European Union (judgment of July 1, 2010, in Case T-321/05, paras. 154–155) and the Court of Justice of the European Union (judgment of December 6, 2012, in Case C-457/10) upheld the European Commission's decision regarding the definition of the relevant market. See also European Commission Decision AT.40394 - *Aspen* of February 10, 2021, paragraphs 26 et seq.

[55] See A524 - *Leadiant Biosciences/drug for the treatment of cerebrotendinous xanthomatosis*, Decision No. 30156 of May 17, 2022, in Bulletin No. 21/2022; A431 - *Ratiopharm/Pfizer*, Decision No. 23194 of January 11, 2012, in Bulletin No. 2/2012; A364 - *Merck-Principi Attivi*, Decision No. 16597 of March 21, 2007, in Bulletin No. 11/2007; and A363 - *Glaxo-Principi Attivi*, Decision No. 15175 of February 8, 2006, in Bulletin No. 6/2006.

[56] The third level of this classification, ATC3, identifies a therapeutic-pharmacological subgroup comprising medicines generally intended for the treatment of the same diseases and which are, in general, interchangeable with one another but not with those belonging to other classes at the first and second levels. The third-level ATC is, therefore, the starting point for identifying interchangeable pharmaceutical products for the purpose of defining the relevant market.

[57] See European Commission Decision M.7275 - *Novartis/GSK Oncology Business* of January 28, 2015, paragraph 208.

CVC/Recordati case[58]).

71. In the present case, it should be noted that the third-level ATC class and fourth-level subclasses are not appropriate for defining the market. On this point, it suffices to note that the same ATC classes used by the NZB (third-level ATC classes L04A– *Immunosuppressants* and Level IV L04AG – *Monoclonal antibodies*) include drugs that act on the immune system and have diverse applications, not limited to multiple sclerosis but intended, more generally, for other immune-related diseases (e.g., *lupus*, rheumatoid arthritis, drugs to reduce the risk of transplant rejection, multiple sclerosis, etc.). Within the same Level III and IV ATC classes, therefore, there are drugs for diseases other than multiple sclerosis for which there is certainly no therapeutic substitutability[59].

72. In general, in *Teva*[60] , the European Commission noted that the emergence of competition similar to that of generic drugs might require a modification of the definition of the relevant market, limiting it to medicines containing the same active ingredient[61].

73. In its precedents regarding multiple sclerosis drugs, the European Commission has distinguished between relapse-preventing therapies (aimed at reducing the duration and residual effects of relapses) and "disease-modifying" therapies (*DMTs*), holding that DMTs do not fall within the same relevant market as relapse-preventing therapies[62] . Furthermore, within the DMT category, a further distinction can be made based on the treatment line (first-, second-, and third-line drugs)[63]. Furthermore, to assess therapeutic substitutability, the European Commission evaluated various aspects such as: (i) patients' therapeutic needs; (ii) the efficacy profile; (iii) the safety profile;

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[58] See European Commission Decisions M.9044 – *CVC/Recordati* of December 4, 2018, paragraph 12; M.9517 – *Mylan/Upjohn* of April 22, 2020, paragraphs 16–17 and 20; and M.9274 – *GSK/Pfizer Consumer Healthcare Business* of July 10, 2019, paragraph 16.

[59] On this point, see European Commission Decision AT.40588 – *Teva Copaxone* of October 31, 2024, in which the Commission conducted an analysis of interchangeability among multiple sclerosis drugs that did not take the ATC class into account.

[60] See European Commission Decision AT.40588 – *Teva Copaxone*, supra.

[61] In this regard, see also the judgment of the Court of Justice of the European Union of January 30, 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 130–131.

[62] See European Commission Decisions M.4049 – *Novartis/Chiron* of February 6, 2006; M.5999 – *Sanofi-Aventis/Genzyme* of January 12, 2011; Case M.7872 – *Novartis/GSK* of December 18, 2015; M.8401 – *Johnson & Johnson/Actelion*, dated June 9, 2017. See also European Commission Decision AT.40588 – *Teva Copaxone*, cit., paragraphs 243.

[63] *See ibid.* With regard to treatment regimens, patients with RRMS typically begin treatment with one of the first-line DMTs. Second-line DMTs are generally indicated only for patients who do not respond to first-line treatments or for patients with rapidly progressing disease. Third-line DMTs are indicated only after a patient has tried one or more second-line treatments and the treatment has failed. The European Commission has determined that second-line DMTs are not interchangeable with a first-line therapy (specifically, Copaxone), as they are not intended for the same patient population.

(iv) tolerability and other factors regarding adverse effects; (iv) evidence regarding patient *switching*[64].

74. In this regard, NZB is a second-line therapy indicated for the treatment of highly active RRMS, defined as: (i) highly active disease despite a complete and adequate course of treatment with at least one DMT; (ii) severe, rapidly evolving RRMS, defined by two or more disabling relapses in one year and one or more enhancing lesions on brain magnetic resonance imaging (MRI) or a significant increase in T2 lesion burden compared to a recent previous MRI[65].

75. In light of the above principles, it is considered *prima facie* possible to define the market for the treatment of multiple sclerosis with *natalizumab* (NZB) based on (i) the characteristics of therapeutic substitutability with other DMTs and (ii) the classification for the purposes of reimbursement and supply.

76. In fact, with regard to therapeutic substitutability, it is observed that other active substances for DMT treatment differ from NZB due to:

a) the authorized indications and *target* populations, which differ among the various products; in particular, the authorization of NZB focuses on highly active RRMS and rapidly progressive RRMS;

b) the different mechanism of action[66], which is reflected in heterogeneous efficacy profiles, response times, and clinical risks, incompatible with a concept of therapeutic equivalence;

c) hospital supply arrangements and classification for reimbursement purposes, which shape demand and determine purchasing procedures[67].

77. Furthermore, switching between NZB and other drugs appears to be limited and is primarily due to the need to discontinue treatment entirely because of the risk of developing related conditions (in particular, PML)[68].

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[64] See *ibid.*

[65] See Docs. 6.11, 6.14.

[66] NZB acts by blocking the migration of immune cells into the central nervous system through the inhibition of integrin α4; anti-CD20 therapies, on the other hand, cause selective depletion of B lymphocytes. Alemtuzumab and cladribine induce, respectively, immune reconstitution and selective lymphocyte depletion. These mechanisms of action result in different timelines, depths, and methods of disease control, with a consequently different impact on relapses, patient disability, and the achievement of *No Evidence of Disease Activity* ("NEDA").

[67] With regard to reimbursement and supply classification, it should be noted that, unlike other drugs, NZB is restricted to hospitals, clinics, and nursing homes; its sale to the public (OSP) is prohibited, and it is classified in reimbursement class H.

[68] This is evident, for example, in the studies on cladribine (see Docs. 10.1, 10.20) and fingolimod (see Doc. 10.18). Furthermore, it appears that in the limited cases of treatment switching due to the need to avoid adverse effects, there would be significant therapeutic differences in cases of treatment modifications and switching to other drugs (see docs. 10.1, 10.17, 10.18, 10.19). In this regard, according to the scientific literature, in cases where patients have discontinued NZB therapy, there is currently no optimal alternative therapy: *"Multiple sclerosis patients who discontinue using natalizumab are at risk of a rebound in disease activity. However, the optimal alternative therapy is not currently known*. […]. *Natalizumab is an effective*

78. Finally, with regard to the geographic market, the standard practice is to consider the competitive scope to be national in scope, given the institutional differences that characterize the healthcare systems and pharmaceutical policies of individual Member States, factors that also appear to prevail in the present case.

III.1.4. Biogen's dominant position in the market for natalizumab-based drugs for the treatment of multiple sclerosis

79. In this market, it should be noted that Biogen accounts for over 70% of sales of natalizumab-based drugs and is the historical incumbent; therefore, it is considered that the company also holds a dominant position in this national market**.**

III.2. *The Alleged Conduct*

80. Biological drugs represent an essential therapeutic resource for the treatment of a variety of serious and debilitating diseases. Due to the costs associated with drug development and production, these medicines impose particularly high costs on the Italian Health Service (SSN). In this context, biosimilar medicines can play a pivotal role by offering the opportunity to ensure access to biologic drugs for all patients who need them while contributing to the financial sustainability of healthcare systems.

81. As is well known, hospital pharmaceutical spending has shown an upward *trend* over time, consistently exceeding budgeted funds. In this context, the marketing of biosimilars can help improve access to medicines by making biologics more sustainable and affordable, triggering market competition and, as a result, promoting price reductions. Furthermore, the savings generated by the use of biosimilars can help finance the cost of reimbursed access to new drugs, making therapeutic innovation increasingly accessible[69].

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treatment for relapsing–remitting multiple sclerosis, but its discontinuation continues to be a complex problem. All of the therapies tried thus far, including fingolimod, have been unable to control the reactivation of the disease. Further studies addressing alternative therapies after natalizumab discontinuation are necessary." (see doc. 10.18).

[69] See AIFA, Second Position Paper on Biosimilar Drugs, March 27, 2018.
In AIFA's periodic monitoring of pharmaceutical spending on biosimilar drugs (cost-saving analysis, September 2025), it is estimated that, depending on the scenarios for the market penetration of biosimilar drugs, cost savings of up to 50% could be achieved. (https://www.aifa.gov.it/documents/20142/3423405/6_Risparmio_biosimilare_set-2025.pdf).

82. The information obtained suggests that Biogen, at least since 2019[70] , has adopted a potentially abusive strategy that—by leveraging the Stratify anti-JC test, in the market for which it holds a dominant position—excludes and/or limits competition from the new entrant Sandoz in the separate market for NZB-based multiple sclerosis drugs, in order to maintain its dominant position in this second market as well.

83. Specifically, the alleged conduct consists of bundling the Stratify test with the drug Tysabry, both from Biogen, and simultaneously refusing to make the Stratify test commercially available to patients receiving Tyruko (a Sandoz drug). In fact, Biogen has never made its test available to those patients, much less on commercial terms that would allow Sandoz to compete.

84. In essence, Biogen's aforementioned conduct has the effect of preventing the use of the Stratify test for patients treated with the competitor's biosimilar drug, Sandoz. This conduct occurs in a context in which Biogen has also (i) filed several divisional patents aimed at tying the Stratify *test* to the specific NZB-based drug, which have been deemed invalid or are pending review, and (ii) Biogen appears to provide healthcare facilities with misleading information intended to artificially limit the perception regarding the possibility of using the Stratify assay even for patients receiving drugs other than Tysabri.

85. Given that the Stratify *test* is the one upon which — thanks to its legal monopoly position — the probability tables for therapeutic decisions regarding the initiation and continuation of NZB-based drug administration were developed — and that this *test* therefore appears to constitute the benchmark *standard* due to the historical nature of the observations that enabled the development of such probability tables — the conduct appears *prima facie* capable of affecting competition in the market for NZB-based multiple sclerosis drugs, hindering actual sales of the competing drug, and thereby nullifying the benefits of biosimilar drugs entering the market in terms of savings for the national healthcare system. It should be noted, in fact, that Sandoz's biosimilar drug results in savings of at least 20% compared to the originator[71].

86. Therefore, the conduct described above, adopted by Biogen since at least 2019 — in short, consisting of the refusal to make the Stratify *test* commercially available for patients receiving Sandoz's Tyruko, including

[70] It would appear that in that year there were pending requests to use the Stratify *test*. Furthermore, note that at least from that year onward, some of the aforementioned divisional patents were filed.

[71] See AIFA, Analysis of Regional Variability (September 2025), p. 99 et seq. https://www.aifa.gov.it/documents/20142/3423405/2_Istogrammi_biologico_biosimilare_set-2025.pdf.

through the combination of the Stratify anti-JCV *test* and the drug Tysabri, both from Biogen — could constitute an abuse of a dominant position in violation of Article 102 of the TFEU.

87. With regard to the attribution of liability for any infringement, in addition to any direct involvement in the alleged violation, Biogen Inc. is in any case liable for the conduct of the companies within the Biogen group in which it holds, directly or indirectly, the entirety of the share capital, in accordance with the simple presumption that, where *"a parent company holds, directly or indirectly, all or almost all of the capital of its subsidiary responsible for a violation of competition rules*," it is presumed that *"such parent company* […] *effectively exercises* [decisive *influence* over the subsidiary's conduct]." This allows the parent company to be held *"responsible for the conduct of the* [subsidiary]"[72] .

IV. EFFECT ON INTRA-EU TRADE

88. According to the European Commission's Communication *"Guidelines on the concept of effect on trade between Member States under Articles 81 and 82 of* the Treaty" (2004/C 101/07), the concept of effect on intra-European trade must be interpreted considering the influence, whether direct or indirect, actual or potential, on trade flows between Member States.

89. The conduct in question appears to fall within the scope of Article 102 of the TFEU, as the strategies allegedly implemented by Biogen affect the entire national market, which constitutes a substantial part of the European Union market, and are, in theory, capable of restricting trade between Member States by hindering competition in the supply of biosimilar medicines containing the active ingredient NZB. Furthermore, it should be noted that both Biogen and Sandoz are multinational companies operating in other European countries.

CONSIDERING, therefore, that the conduct engaged in by Biogen Italia S.r.l. and Biogen Inc., or in any event attributable to them, for the reasons set forth above, appears to constitute a violation of Article 102 TFEU;

[72] See, *inter alia*, Court of Justice of the European Union, judgment of January 27, 2021, *The Goldman Sachs Group Inc. v. Commission*, C-595/18 P, EU:C:2021:73, para. 32; as well as Council of State, Section VI, judgment of January 11, 2023, No. 376. The Court of Justice of the European Union has more generally clarified that *"the concept of 'undertaking' and, through it, that of 'economic unit' imply ipso iure joint and several liability among the entities comprising the economic unit at the time the infringement was* committed" (Court of Justice of the European Union, judgment of October 6, 2021, *Sumal SL*, C-882/19, EU:C:2021:800, para. 44).

RESOLVES

a) to initiate an investigation, pursuant to Article 14 of Law No. 287 of October 10, 1990, against Biogen Italia S.r.l. and Biogen Inc. to ascertain the existence of violations of competition under Article 102 of the TFEU;

b) to set a deadline of sixty days, starting from the date of notification of this decision, for the legal representatives of the parties to exercise their right to be heard, specifying that the request for a hearing must be received by the Manufacturing, Agri-Food, Pharmaceuticals, and Commercial Distribution Division of the Competition Department – 2 of this Authority at least fifteen days prior to the expiration of the aforementioned deadline;

c) that the person in charge of the proceedings is Dr. Luigi Di Gaetano;

d) that the case files may be inspected at the Manufacturing, Agri-Food, Pharmaceutical, and Commercial Distribution Directorate of the Competition Department – 2 of this Authority by the legal representatives of the parties or by persons delegated by them;

e) that the proceedings must be concluded by December 31, 2027.

This order shall be served on the interested parties and published in the Bulletin of the Italian Competition and Market Authority.

THE SECRETARY GENERAL
Guido Stazi

THE *ACTING* CHAIRPERSON
Elisabetta Iossa