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ANALYSIS OF DECISIONS NOT TO INCORPORATE BIOLOGICAL DRUGS IN RHEUMATOLOGY BY CONITEC*

ANÁLISE DAS DECISÕES DE NÃO INCORPORAÇÃO DE MEDICAMENTOS BIOLÓGICOS EM REUMATOLOGIA PELA CONITEC

ANÁLISIS DE LAS DECISIONES DE NO INCORPORACIÓN DE FÁRMACOS BIOLÓGICOS EN REUMATOLOGÍA POR PARTE DEL CONITEC

CRediT

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ABSTRACT
Biological medicines have revolutionised the treatment of several conditions, such as autoimmune rheumatic diseases (ARD), but their high production and research costs pose challenges to the sustainability of healthcare systems. This work identified and analysed the reasons that led to the non-incorporation of biological medicines submitted for evaluation by the National Commission for the Incorporation of Technologies (CONITEC) in the Unified Health System (SUS), used in the pharmacotherapy of some ARDs. A descriptive, observational, and retrospective study was carried out on reports recommending therapies related to ARDs, issued by CONITEC from 2019 to 2024, analysing only reports recommending non-incorporation. The variables analysed were type of technology, origin of demand, indication, preliminary recommendation, existence of public consultation (PC), and final recommendation of the commission. Twelve reports were identified, of which nine resulted in deliberations unfavourable to the inclusion of biological medicines for AKI. The biologics not incorporated were secukinumab, ixekizumab, certolizumab pegol and intravenous belimumab. The most considered decision criteria were effectiveness/safety (67%) and budgetary impact (78%). The results obtained reinforce the importance of systematised evaluations, based on more transparent criteria for the inclusion of technologies in the SUS.

KEYWORDS: Biological Products; Rheumatic Diseases. Autoimmune Diseases; Technology Assessment, Biomedical**.**

RESUMO
Os medicamentos biológicos têm revolucionado o tratamento de diversas condições, como as doenças reumáticas autoimunes (DRA) mas seus elevados custos de produção e pesquisa representam desafios para a sustentabilidade dos sistemas de saúde. Este trabalho identificou e analisou as razões que levaram à não incorporação de medicamentos biológicos submetidos à avaliação da Comissão Nacional de Incorporação de Tecnologias (CONITEC) no Sistema Único de Saúde (SUS), usados na farmacoterapia de algumas DRA. Foi realizado um estudo descritivo, observacional e retrospectivo dos relatórios de recomendação de terapias relacionadas às DRA, emitidos pela CONITEC no período de 2019 a 2024, analisando-se apenas os relatórios com recomendação de não incorporação. As variáveis analisadas foram tipo de tecnologia, origem da demanda, indicação, recomendação preliminar, existência de consulta pública (CP) e recomendação final da comissão. Identificou-se 12 relatórios, dos quais 9 resultaram em deliberações desfavoráveis à inclusão dos medicamentos biológicos para DRA. Os biológicos não incorporados foram o secuquinumabe, ixequizumabe, certolizumabe pegol e belimumabe intravenoso. Os critérios de decisão mais considerados foram eficácia/segurança (67%) e impacto orçamentário (78%). Os resultados obtidos reforçam a importância de avaliações sistematizadas, baseadas em critérios mais transparentes para a inserção de tecnologias no SUS.

DESCRITORES: Produtos Biológicos; Doenças Reumáticas; Doenças Autoimunes; Avaliação da Tecnologia Biomédica.

RESUMEN
Los medicamentos biológicos han revolucionado el tratamiento de enfermedades reumáticas autoinmunes (ERA), pero sus elevados costos plantean desafíos para la sostenibilidad de los sistemas sanitaríos. Este trabajo identificó y analizó los motivos de la no incorporación de medicamentos biológicos sometidos a evaluación por la Comisión Nacional de Incorporación de Tecnologías (CONITEC) en el Sistema Único de Salud (SUS), utilizados en la farmacoterapia de algunas ERA. Se realizó un estudio descriptivo, observacional y retrospectivo de los informes de recomendación de terapias relacionadas con las ERA, emitidos por el CONITEC de 2019 a 2024, analizando únicamente los informes de no incorporación. Las variables analizadas fueron tipo de tecnología, origen de la demanda, indicación, recomendación preliminar, existencia de consulta pública y recomendación final de la comisión. Se identificaron 12 informes, de los cuales 9 resultaron en deliberaciones desfavorables a la inclusión de medicamentos biológicos para la IRA. Los biológicos no incorporados fueron secukinumab, ixekizumab, certolizumab pegol y belimumab intravenoso. Los criterios de decisión más considerados fueron la eficacia/seguridad (67%) y el impacto presupuestario (78%). Los resultados refuerzan la importancia de evaluaciones sistematizadas, basadas en criterios más transparentes para la inclusión de tecnologías en el SUS.

DESCRIPTORES: Productos Biológicos; Enfermedades Reumáticas; Enfermedades Autoinmunes; Evaluación de la Tecnología Biomédica.

1 INTRODUCTION

Biological medicines have revolutionised the treatment of several diseases, especially those that do not respond adequately to conventional therapies[1]. They are obtained from biological fluids, animal tissues, or biotechnological procedures through manipulation or genetic modification techniques[2]. In recent decades, their evolution in the global market has been marked by rapid growth[1]. In Brazil, between 2020 and 2022, revenues from this class increased by 43.4%, reaching more than BRL 34.0 billion and representing 25.9% of the total pharmaceutical market. The total number of marketed presentations grew by 10.8%, the number of active ingredients by 8.6%, and the number of therapeutic classes by 1.1%. In 2020, 282 products were marketed; in 2021, 297; and in 2022, 310, reflecting an overall growth of 9.9%[2].

The increasing demand for these technologies highlights a significant challenge regarding their accessibility, financing, and regulation within the Brazilian Unified Health System (SUS)[3]. Their prices impose substantial financial pressure on the public budget, which is subject to fiscal constraints[4]. SUS has managed the incorporation of new health technologies to optimise the use of public resources and ensure that investments are directed towards innovations relevant to citizens[3]. This task is carried out by the National Commission for the Incorporation of Technologies in the Unified Health System (CONITEC), an advisory body that supports the Ministry of Health (MS) in the incorporation, exclusion, or modification of health technologies within SUS[4,5].

Mosegui et al. point out that, over the past 20 years, biological medicines have transformed the treatment of rheumatic diseases (RDs), particularly rheumatoid arthritis (RA). However, their high cost represents a challenge for both individuals and health systems[6]. This study aims to analyse the reasons for the non-incorporation of biological medicines used in the treatment of autoimmune rheumatic diseases (ARDs), focusing on RA, systemic lupus erythematosus (SLE), psoriatic arthritis (PsA), and ankylosing spondylitis (AS), as assessed by CONITEC between 2019 and 2024.

2 THEORETICAL FRAMEWORK

The introduction of health technologies is a major challenge and has the potential to strengthen the sustainability of public policies. However, it requires a thorough analysis of the disease burden, clinical benefit, safety, level of innovation, quality of evidence, cost-effectiveness, budgetary impact, and other relevant sources of information[3]. Within SUS, this approach has enabled the efficient allocation of resources based on the principles of Health Technology Assessment (HTA). In HTA, decision criteria are defined as essential elements to guide the deliberative process, which involves the simultaneous analysis of multiple aspects[3].

Established in 2011 after the approval of Law No. 12.401/2011, CONITEC advises the Ministry of Health (MS) on matters related to the incorporation, modification, and exclusion of health technologies within the scope of SUS[4]. The demands submitted to the commission may come from any party interested in including technologies in the SUS formulary – from external applicants (scientific societies, patient organisations, manufacturers, and industries producing devices and medicines, among other institutions) to internal ones

(governmental bodies or institutions within the MS structure, such as MS secretariats, federal health institutes, federal hospitals, and other MS-affiliated agencies)[5].

The information obtained in technology analyses is compiled into recommendation reports – documents designed to assist in selecting which technologies will be adopted by SUS. These reports are prepared after a critical assessment of the scientific evidence presented in the dossier[3]. The evaluative process follows a defined sequence that results in an initial recommendation, which is published prior to the public consultation (PC). This step allows the public to understand the preliminary stance of the commission's plenary[4]. The final recommendation, as the name suggests, is the last stage of the process, ratified by the Secretary of Science, Technology, and Strategic Health Inputs (SCTIE), formalised through a ministerial ordinance, and concluding with the final deliberation, which has two mutually exclusive possibilities: (1) maintenance of the preliminary position; or (2) modification/reversal of the initial recommendation[4].

The result is published in the *Diário Oficial da União* (DOU) and made available on the CONITEC website for public access[5]. Once the ordinance is published, the population can access the medicines or procedures incorporated and previously evaluated by CONITEC's plenary.

3 METHODOLOGY

This is a descriptive, observational, and retrospective study with a qualitative and quantitative approach, based on publicly accessible secondary data and document analysis. The study analysed the reasons related to the non-recommendations for the incorporation of biological agents used in the most prevalent autoimmune rheumatic diseases (ARDs) in Brazil – such as rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), psoriatic arthritis (PsA), and ankylosing spondylitis (AS) – as published by CONITEC between 2019 and 2024. The method was based on the studies of Lopes and collaborators and Ribeiro and collaborators[4,7].

The work was organised into three main stages: (1) extraction and updating of data related to biological medicines used in the therapy of autoimmune rheumatic diseases; (2) identification and description of situations in which their recommendation was denied; and (3) specific analysis of the cases in which a non-incorporation recommendation was issued by CONITEC[4].

The main data source for obtaining public information was the technical recommendation reports published by the commission, available on the CONITEC website[4,8,9]. Ministerial ordinances referring to these non-incorporations were also analysed. The sample included biological medicines indicated for ARD therapy that received a non-incorporation recommendation, published by CONITEC between 1 January 2019 and 31 September 2024. Only recommendation reports referring to technologies classified as medicines, submitted to the commission within the field of rheumatology during the study period, were analysed.

All reports related to ARD therapies were read, quantified, and data were extracted, encompassing biologics that received recommendations for incorporation, non-incorporation, exclusion, or alteration/expansion of use. The medicines involved in non-incorporation recommendations were identified, and these cases were described. Data were tabulated on technology type, demand origin, indication, preliminary recommendation,

whether a PC was conducted, and the final recommendation related to the non-incorporations. Quantification and evaluation of the type of justification supporting each negative decision were also performed.

The distribution of denials was categorised according to the year in which the ordinances were published. For example, in 2019, four ordinances were published related to four recommendations deliberated in that year for two technologies. Of these four decisions, two were for non-incorporation into SUS, and their ordinances (SCTIE/MS Nos. 52/2019 and 54/2019) were published in the *Diário Oficial da União* (DOU) No. 215, Section 1, page 195, on 6 November 2019[8,9].

As in the studies by Lopes, Luiza, and Silva, the final reports were analysed to identify the main justification that supported CONITEC's final recommendation, classifying them into major categories: (1) economic (treatment cost, price negotiation, taxation); (2) clinical (survival, clinical effectiveness, etc.); (3) both (economic and clinical); and (4) unclear[4]. The information from each report was collected and described. Data compilation and analysis were performed using Microsoft Office Excel spreadsheets.

This study did not require approval by a Research Ethics Committee, as it was based on publicly available data and did not involve patient records.

4 DISCUSSION AND ANALYSIS OF RESULTS

Between January 2019 and September 2024, CONITEC deliberated on 12 recommendations/reports regarding requests for the incorporation of biological medicines used in the treatment of autoimmune rheumatic diseases (ARDs) [8–18]. No requests were found for the exclusion of this class of drugs.

The same technology could have been submitted more than once for various reasons, such as different therapeutic indications (for example, secukinumab was submitted multiple times for distinct indications in 2019 and 2021); rejections in previous analyses (in 2019, secukinumab was denied incorporation, and in 2021, a new submission for the same clinical indication was again rejected); requests from different applicants at different times (in 2020, Lilly do Brasil Ltda. submitted ixekizumab, while in 2024, the Secretariat for Science, Technology, Innovation, and the Health Industrial Complex – SECTICS – submitted two requests for the same drug); or due to the need to readjust the target population[8–10,12,13,15,18].

During this period, five biologics were submitted for CONITEC evaluation: intravenous belimumab, certolizumab pegol, ixekizumab, rituximab, and secukinumab. These medicines presented 12 different indications for five ARDs (PsA, SLE, axial spondyloarthritis – radiographic and non-radiographic – and ANCA-associated vasculitis). Table 1 presents the technologies, indications, demand sources, types of requests, decisions, and corresponding ordinances for each recommendation.

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Table 1 – Biological medications used in autoimmune rheumatic diseases, analysed by CONITEC between 2019 and 2024.

Technology (generic name)	Indication	Applicant	Type of Demand	Decision (and opinion date)	Ordinance
Secukinumab	Treatment of active PsA in adult patients in the first line of biological therapy	Novartis Biociências S.A.	Use expansion	Not to incorporate into SUS (10/09/19)	SCTIE/MS nº 52/2019 – Published on 11/06/2019
Secukinumab	Treatment of PsA in adult patients with inadequate response to synthetic DMARDs (sDMARDs) or biological anti-TNF class	Novartis Biociências S.A.	Incorporation	Incorporate into SUS (12/05/18)	SCTIE nº 01/2019 -- Published on 01/21/2019
Certolizumab Pegol	Treatment of PsA	UCB Biopharma S.A.	Incorporation	Incorporate into SUS (10/09/19)	SCTIE/MS nº 59/2019 – Published on 11/20/2019
Secukinumab	First line of biological therapy for the treatment of active AS in adult patients	Novartis Biociências S.A.	Incorporation	Not to incorporate into SUS (10/09/19)	SCTIE/MS nº 54/2019 – Published on 11/06/2019
Ixekizumab	Treatment of adult patients with active PsA with insufficient response or intolerance to treatment with one or more DMARDs	Eli Lilly do Brasil Ltda.	Incorporation	Not to incorporate into SUS (08/06/20)	SCTIE/MS nº 31/2020 – Published on 08/20/2020
Certolizumab pegol	Treatment of PsA in the first line of biological treatment with biological disease-modifying antirheumatic drugs (bDMARDs)	UCB Biopharma Ltda.	Use expansion	Not to incorporate into SUS (06/09/21)	SCTIE/MS nº 39/2021 – Published on 07/08/2021
Secukinumab	First line of biological therapy for the treatment of axSpA in adult patients	Novartis Biociências S.A.	Incorporation	Not to incorporate into SUS (06/10/21)	SCTIE/MS nº 37/2021 – Published on 07/08/2021
Secukinumab	Treatment of active PsA in adult patients in the first line of biological therapy	Novartis Biociências S.A.	Incorporation	Not to incorporate into SUS (05/05/2021)	SCTIE/MS nº 27/2021 – Published on 06/02/2021
Rituximab	Remission induction therapy for patients with a recent diagnosis of childbearing age and for cases of relapse of ANCA-associated vasculitis, classified as GPA and MPA, active and severe	Sociedade Brasileira de Reumatologia	Incorporation	Incorporate into SUS (06/29/23)	SECTICS/MS nº 44/2023 – Published on 07/28/2023
Belimumab intravenous	Adjuvant treatment of adult patients with SLE with high disease activity despite standard therapy, and who have experienced therapeutic failure with two previous immunosuppressants	GlaxoSmithKline Brasil Ltda.	Incorporation	Not to incorporate into SUS (03/28/23)	SECTICS/MS nº 37/2023 – Published on 06/30/2023
Ixekizumab	Treatment of adults with axSpA with prior inadequate response or intolerance to Tumor Necrosis Factor inhibitors (anti-TNF)	SECTICS/MS	Incorporation	Not to incorporate into SUS (07/03/24)	SECTICS/MS nº 36/2024 – Published on 08/23/2024
Ixekizumab	Treatment of adults with radiographic and non-radiographic axSpA who have not responded to conventional therapy with non-steroidal anti-inflammatory drugs (NSAIDs)	SECTICS/MS	Incorporation	Not to incorporate into SUS (07/03/24)	SECTICS/MS nº 35/2024 – Published on 08/23/2024

Source: Data from research**. Abbreviations used:** PsA = Psoriatic Arthritis (AP), AS = Ankylosing Spondylitis (EA), axSpA = Axial Spondyloarthritis (EpAs), DMARDs = Disease-Modifying Antirheumatic Drugs (MMCD), SLE = Systemic Lupus Erythematosus (LES), GPA = Granulomatosis with Polyangiitis, MPA = Microscopic Polyangiitis.

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There were 12 recommendations between 2019 and 2024 – four in the first year, one in the second, three in 2021, none in 2022[8–15]. In the last two years, four recommendations were issued[16–18]. All submissions in the first three years were made by representatives of the pharmaceutical industry (external applicants)[8–15]. In 2023, requests came from external applicants such as medical societies and the pharmaceutical sector (the main applicant)[16,17]. In the final year, the requests were made by SECTICS, considered an internal applicant.[18]

Of the 2019 deliberations, two were for incorporation (certolizumab pegol and secukinumab)[10,11], and two were for non-incorporation into SUS (secukinumab)[8,9]. The only drug with a non-incorporation decision in 2020 was ixekizumab, indicated for the pharmacotherapy of adult patients with active PsA[12]. Secukinumab and certolizumab pegol were denied incorporation in 2021, and no biologics for ARDs were approved in 2022[13–15]. In 2023, rituximab was recommended for incorporation, while intravenous belimumab was denied[16,17]. Ixekizumab received two non-incorporation recommendations in 2024 for the treatment of axial spondyloarthritis, covering two different indications[18].

In summary, there were nine non-incorporation recommendations (75%), of which two were for expanded use, three for incorporation, and none for exclusion (Table 1)[8–18].

Textual analysis of the final recommendations in the included reports identified the main justifications for CONITEC's negative opinions, which were identified and categorised as economic, clinical, both, or unclear (Table 2).

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Table 2 – Biological medications used in autoimmune rheumatic diseases, with recommendations for non-incorporation into SUS, between 2019 and 2024.

Type of Technology	Indication	Origin of Demand	Initial Recommendation	Public Consultation	Final Recommendation	Central Theme of Final Opinion	Ordinance
2019							
Secukinumab	First line of biological therapy for the treatment of active AS in adult patients	External	Non-incorporation	Topic submitted for public consultation	Not to incorporate into SUS	Clinical	SCTIE/MS nº 54/2019 – Published on 11/06/2019
Secukinumab	Treatment of active PsA in adult patients in the first line of biological therapy	External	Use expansion	Topic submitted for public consultation	Not to incorporate into SUS	Economic	SCTIE/MS nº 52/2019 – Published on 11/06/2019
2020							
Ixekizumab	Treatment of adult patients with active PsA with insufficient response or intolerance to treatment with one or more DMARDs	External	Non-incorporation	Topic submitted for public consultation	Not to incorporate into SUS	Clinical	SCTIE/MS nº 31/2020 – Published on 08/20/2020
2021							
Certolizumab pegol	Treatment of PsA in the first line of biological treatment with bDMARDs	External	Unfavourable to use expansion	Topic submitted for public consultation	Not to incorporate into SUS	Both[1]	SCTIE/MS nº 39/2021 – Published on 07/08/2021
Secukinumab	First line of biological therapy for the treatment of axSpA in adult patients	External	Unfavourable to incorporation	Topic submitted for public consultation	Not to incorporate into SUS	Both[1]	SCTIE/MS nº 37/2021 – Published on 07/08/2021
Secukinumab	Treatment of active PsA in adult patients in the first line of biological therapy	External	Unfavourable to incorporation	Topic submitted for public consultation	Not to incorporate into SUS	Economic	SCTIE/MS nº 27/2021 – Published on 06/02/2021
2023							
Belimumab intravenous	Adjuvant treatment of adult patients with SLE with high disease activity despite standard therapy, and who have experienced therapeutic failure with two previous immunosuppressants	External	Unfavourable to incorporation	Topic submitted for public consultation	Not to incorporate into SUS	Economic	SECTICS/MS nº 37/2023 – Published on 06/30/2023
2024							
Ixekizumab	Treatment of adults with axSpA with prior inadequate response or intolerance to anti-TNF	Internal	Unfavourable to Incorporation	Topic submitted for public consultation	Not to incorporate Into SUS	Both[1]	SECTICS/MS nº 36/2024 – Published on 08/23/2024
Ixekizumab	Treatment of adults with radiographic and non-radiographic axSpA who have not responded to conventional therapy with NSAIDs	Internal	Unfavourable to incorporation	Topic submitted for public consultation	Not to incorporate into SUS	Both[1]	SECTICS/MS nº 35/2024 – Published on 08/23/2024

Source: Research data (2025). **Legend:** [1]Both (economic and clinical)

The technology with the highest number of submissions and unfavourable recommendations was secukinumab 150 mg/mL (Cosentyx), submitted by Novartis Biociências S.A.[8,9,13,15]. Of the four requests, two were for the treatment of axial spondyloarthritis (AxSpA) and two for PsA. In 2019, its use was proposed as the first stage of biological therapy for adults with active AS or PsA who had not adequately responded to conventional therapy with DMARDs and NSAIDs[8,9]. In 2021, it was proposed as first-line biological therapy for adult patients with active PsA and for the treatment of radiographic and non-radiographic AxSpA[13,15]. For ixekizumab 80 mg/mL (Taltz), by Eli Lilly and Company, there were three denials. The first request, in 2020, came from the company itself for the treatment of adults with active PsA with an insufficient response or intolerance to one or more DMARDs; the other two, in 2024, were submitted by SECTICS/MS for the pharmacotherapy of adults with AxSpA with prior inadequate response or intolerance to anti-TNF agents, and for adults with radiographic and non-radiographic AxSpA who had not responded to conventional therapy with NSAIDs[12,18].

In all cases, CONITEC forwarded the topic to public consultation, but the plenary concluded that there was insufficient evidence to modify the preliminary recommendation. The initial decision was maintained in eight (89%) of the evaluation processes[9,12,13–16,18]. In only one situation was the initial favourable decision reversed after public input. This case referred to the 2019 request for expanded use of secukinumab for PsA, where uncertainties remained regarding the proportion of PsA patients with concomitant moderate-to-severe psoriasis who would use the drug in SUS at the 300 mg dose as first-line biological therapy[8].

Regarding the main themes underlying the final negative decisions, four (44%) were based on both clinical and economic grounds (‘both’), as defined in this study. These decisions indicated that the technologies were neither superior (in efficacy and safety) nor economically advantageous compared to other biologics already available in SUS, and that the incremental costs estimated in cost-minimisation and budget impact analyses were high for the proposed indications. The medicines included in this category were ixekizumab, certolizumab pegol, and secukinumab[14,15,18]. Two cases (22%) were based on clinical factors, as no additional benefits in effectiveness or safety were demonstrated compared to therapies already available in SUS, involving ixekizumab and secukinumab[9,12]. Three cases (33%) were based on economic justifications, considering that the incremental budget impact exceeded estimates and could compromise SUS sustainability without evidence of additional clinical benefits. These included belimumab and secukinumab[8,13,16]. No unclear justifications were identified.

The analysis sought to identify and evaluate the reasons considered by CONITEC in the processes that resulted in non-incorporation recommendations for biologics used in the management of ARDs (RA, SLE, PsA, and AS) between 2019 and 2024. The highest number of recommendation reports was in 2019 and 2021, with four and three reports, respectively[8–11,13–15]. Non-incorporation recommendations were predominant. Campolina, Yuba, and Soárez analysed CONITEC oncology reports and found that medicines represented the most frequently evaluated technology type between 2012 and 2018, with 2013 and 2014 being the years with the highest concentration of reports[3].

Seventy-eight percent (7/9) of the requests between 2019 and 2023 were external, primarily from the pharmaceutical industry[8,9,12,13–16]. In 2024, internal applicants played a more active role, indicating increased government interest in evaluating technologies aligned with the strategic needs of SUS. In a study on the incorporation of new medicines by CONITEC between 2012 and 2016, Caetano et al. suggested that 40.9% of external requests came from the pharmaceutical sector, while internal submissions accounted for 52.2% of total drug-related requests. Internal-origin requests had a higher rate of favourable recommendations, representing 82.8% of all incorporations[5].

Some biologics were subject to multiple submissions during the study period, either for different clinical indications, due to prior unfavourable recommendations, or because of early process termination[8–10,12,13,15,18]. This recurrence of submissions – often within short intervals and without significant new clinical evidence – raises concerns about the efficiency and sustainability of CONITEC's evaluation process. Beyond constituting potential institutional rework, such practices represent a considerable opportunity cost by consuming time and technical resources that could be directed towards technologies with greater potential impact for SUS[3–5].

This scenario underscores the importance of establishing clearer and more objective guidelines for the resubmission of previously evaluated technologies, requiring the unequivocal demonstration of new and robust evidence, such as additional clinical trial results or real-world data with significant clinical impact. Proposals such as defining minimum intervals between submissions and implementing preliminary technical screening of clinical justifications could improve the process, preventing undue prioritisation of sectoral interests over the strategic needs of the public health system[3–5].

Caetano et al. highlighted that antineoplastics and immunomodulatory agents accounted for more than one-third of the medicines incorporated into SUS between 2012 and 2016 and were also the most frequent group among those with unfavourable recommendations[5]. These findings are consistent with Araujo et al., who similarly reported a predominance of immunomodulators and antineoplastics between 2015 and 2019, with monoclonal antibodies and anti-TNF agents being the most frequently requested[1].

No significant differences were observed regarding changes in the commission's opinions. Although all requests were submitted to public consultation, only one resulted in a reversal of the initial decision[8]. In most cases, the preliminary recommendations were upheld, suggesting that despite meaningful public engagement, CONITEC's deliberations remain strongly guided by technical criteria – a finding consistent with Caetano et al.[5].

A study on the reversal of CONITEC recommendations after public consultation, conducted by Lopes, Luiza, and Silva, reported that between 2012 and 2017, the proportion of simplified processes decreased from 57.4% in 2013 to 21.1% in 2017. Of the 307 medicines analysed, 205 (66.8%) underwent public consultation. Most reversals were related to antineoplastics and immunomodulators, and all simplified processes originated internally within the MS[4].

Regarding the main themes or justifications for negative recommendations, the most frequently cited criteria were efficacy/safety and budgetary impact[8,9,12,13–16,18]. In the only case where the initial recommendation changed after public consultation, the justification was economic, focusing on the unit cost of the drug and

incremental budget impact. Understanding the reasoning behind these decisions is essential for making the selection process more systematised, explicit, and collectively discussed. Given the significant rise in healthcare spending, it is crucial to adopt transparent and explicit criteria for resource prioritisation, ensuring legitimacy in the incorporation of new health technologies[3,4].

5 FINAL CONSIDERATIONS

This study evaluated the recommendations issued by CONITEC regarding biological medicines used for autoimmune rheumatic diseases (ARDs) between 2019 and 2024, revealing a predominance of unfavourable deliberations towards incorporation. Economic and clinical factors were frequently used to justify the non-incorporation decisions, particularly the budgetary impact and the absence of significant additional clinical benefits compared with therapies already available in SUS.

The predominance of external applicants, especially from the pharmaceutical industry, reflected the sector's interest in expanding access to its technologies within the public system. However, the increased participation of internal applicants in 2024 may indicate a more strategic governmental orientation towards evaluating technologies that align with SUS priorities.

The commission's deliberations proved to be strongly based on technical criteria – such as efficacy, safety, cost-effectiveness, and budgetary impact – while the social engagement promoted through public consultations contributed to enhancing the transparency and legitimacy of the process. Public participation does not oppose technical decisions but rather complements them, reinforcing the importance of greater clarity and accessibility in decision-making processes to ensure that demands align with the real needs of patients and public health.

The results highlight the importance of systematised evaluations based on transparent criteria for the inclusion of technologies within SUS, incorporating detailed analyses of safety, efficacy, and financial impact. They also emphasise the need for constructive dialogue among the different actors involved in the decision-making process, with the goal of strengthening the scientific basis and legitimacy of the decisions made – particularly in the context of increasing pressure on public health budgets.

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