ABSTRACT

OBJECTIVE: To analyze the access and utilization profile of biological medications for psoriasis provided by the judicial system in Brazil.

METHODS: This is a cross-sectional study. We interviewed a total of 203 patients with psoriasis who were on biological medications obtained by the judicial system of the State of Sao Paulo, from 2004 to 2010. Sociodemographics, medical, and political-administrative characteristics were complemented with data obtained from dispensation orders that included biological medications to treat psoriasis and the legal actions involved. The data was analyzed using an electronic data base and shown as simple variable frequencies. The prescriptions contained in the lawsuits were analyzed according to legal provisions.

RESULTS: A total of 190 lawsuits requesting several biological drugs (adalimumab, efalizumab, etanercept, and infliximab) were analyzed. Patients obtained these medications as a result of injunctions (59.5%) or without ever demanding biological medication from any health institution (86.2%), i.e., public or private health services. They used the prerogative of free legal aid (72.6%), even though they were represented by private lawyers (91.1%) and treated in private facilities (69.5%). Most of the patients used a biological medication for more than 13 months (66.0%), and some patients were undergoing treatment with this medication when interviewed (44.9%). Approximately one third of the patients discontinued treatment due to worsening of their illness (26.6%), adverse drug reactions (20.5%), lack of efficacy, or because the doctor discontinued this medication (13.8%). None of the analyzed medical prescriptions matched the legal prescribing requirements. Clinical monitoring results showed that 70.3% of the patients had not undergone laboratory examinations (blood work, liver and kidney function tests) for treatment control purposes.

CONCLUSIONS: The plaintiffs resorted to legal action to get access to biological medications because they were either unaware or had difficulty in accessing them through institutional public health system procedures. Access by means of legal action facilitated long-term use of this type of medication through irregular prescriptions and led to a high rate of adverse drug reactions as well as inappropriate clinical monitoring.

DESCRIPTORS: Psoriasis. Antibodies, Monoclonal, therapeutic use. Pharmaceutical Services, legislation & jurisprudence. Judicial Decisions. Equity in Access.
Psoriasis (PSO) is a recurrent, inflammatory, genetic, and chronic disease characterized by epidermal proliferation and inflammation. This disease causes scaly and erythematous lesions that target the skin, nails, and joints. The prevalence rates vary between 0.6% and 4.8% and equally affect men and women of all races. Despite showing benign progression, worsening of the conditions causes significant physical and psychological morbidity and has a major impact on the patient’s quality of life. The treatment is based on the criteria of the Psoriasis Area Severity Index (PASI) and in the impact on the quality of life with respect to disease remission or increase in the period free of skin lesions. According to the national therapeutic guidelines and international guidelines, the treatment of moderate to severe PSO should begin with phototherapy. In case of failure,
treatment should be continued with systemic medications (e.g., methotrexate, acitretin, and cyclosporine) before proceeding with the biological medications (e.g., etanercept, infliximab, and adalimumab). The Protocolo Clínico e Diretrizes Terapêuticas (PCDT – Clinical Protocol and Therapeutic Guidelines) for the treatment of PSO in the Public Health System (SUS) was published in 2013. The treatment excludes biological medications and follow-up includes clinical monitoring of the evolution of disease and analysis of adverse drug reactions.

The access to biological medicines is achieved through the judicial system or via administrative means, which makes it difficult to plan and manage the expenses involved. The latter is implemented by some health departments to request medications that are not available at SUS but both generate a conflict regarding the principle of comprehensiveness proposed by SUS.

The process that plaintiffs undergo to obtain access to biological medications is challenging, and the data pertaining to drug use, prescription, and effects (results and safety) are scarcely available. In addition, the documentation regarding the judicialization process is rarely disclosed in this type of study. Therefore, the purpose of our study was to analyze the access and utilization profile, obtained by judicial means, of biological medications for the treatment of PSO in Brazil.

**METHODS**

We performed a descriptive cross-sectional study with patients with PSO who were either undergoing treatment or had been treated with biological medications by means of judicial actions against the state of Sao Paulo between 2004 and 2010.

The dispensation orders (DO) containing the biological medication to be supplied per patient with PSO (International Classification of Diseases – ICD-L40), which was made available by the court control system of the Sao Paulo State Health Department (SCJ/SES-SP), provided an estimate of the population under treatment in the referred period. The following variables were collected: contested medication, author and type of action, and sociodemographic characteristics of the plaintiff and prescriber.

After locating corresponding records, we analyzed the documents presented to the court with information regarding the medical report, prescription, legal representation, type of injunction, appointed justice system, defendant, civil or district court, and the origin of prescription.

Patients who had retrieved and used biological medication during our study period and were willing to participate were included. They were found through injunctions filed against the state government, with a judicial decision in favor of the authors in any instance that were submitted to 14 public circuit courts of the capital of the State of Sao Paulo. We excluded patients who provided their contact as their lawyer’s office number, those who were not located after five attempts, and deceased patients.

Telephone contact was elected because it is effective and inexpensive. All interviews were performed using the computer-assisted telephone interviewing technique, with the use of a microcomputer coupled to a telephone device with a headset; specific management and recording software were connected simultaneously. This apparatus allows monitoring interviews, avoiding inconsistencies in the questionnaire and developing features related with research management such as automatic control of follow-up calls, control of time per interview/interviewer, remote listening system, and real time control.

We developed a Microsoft Office Access® electronic form, based on the instrument used for the interviews with 16 screens to record the data. The language of the questionnaire was adapted for a telephone conversation. The team of interviewers was previously trained to standardize language and interview time.

The questionnaire included the following information: patient, type of medical assistance, access to medication for the treatment of PSO before the injunction, participation in a support group, meetings with the lawyer, contact with the pharmaceutical manufacturer, evolution of the disease, and use of medicine (time involved in diagnosis and treatment), provided pharmacotherapy follow-up, and suspected adverse drug reactions. This instrument was previously validated by rheumatology and public health experts. The SCI/SES-SP data, regarding injunctions and interviews, were organized in an electronic spreadsheet. The data was analyzed with the 2013 version of Excel® software, and the results were shown as simple variable frequencies. The quality control of data collection was achieved by periodic crosschecking of information, which was performed by one of the researchers who was not part of the on-the-spot data collection.

The prescriptions involved in the proceedings were analyzed in terms of legal provisions of the Law 5.991/1973. Data collection was authorized by the Health Department of Sao Paulo State. This study was approved by the Research Ethics Committee of the University of Sorocaba (Protocol 011/2009 of August 17, 2009), according to

---

4 Ministério da Saúde, Secretaria de Atenção à Saúde. Portaria nº 1.229, de 5 de novembro de 2013. Aprova o Protocolo Clínico e Diretrizes Terapêuticas da Psoríase. Diário Oficial Uniao. 6 nov 2013;Seção 1:52.

5 For those interested in the questionnaire, please contact the authors.

6 Presidência da República. Lei nº 3.991, de 17 de dezembro de 1973. Dispõe sobre o Controle Sanitário do Comércio de Drogas, Medicamentos, Insumos Farmacêuticos e Correlatos, e dá outras Providências. Brasília [DF]; 1973[cited 2014 Mar 31]. Available from: http://www.planalto.gov.br/ccivil_03/lei/L5991.htm
Resolution 196/96 of the National Health Council. All participants signed the informed consent form.

RESULTS
A total of 25,184 DO were analyzed regarding the lawsuits filed to obtain medication and other health products between 2004 and 2010. Of 218 identified patients, 11 did not meet the inclusion criterion and 4 were excluded. Of 203 interviewed plaintiffs, 190 processes were located (Figure).

Adalimumab, etanercept, infliximab, and efalizumab were part of these DO. The sociodemographic characteristics and the process toward access to a biological medicine are described in Table 1. A total of 44.9% patients used a biological medicine, of which 89.7% never requested the medicine to SUS before filing a lawsuit. Patients with access to private medical care (69.5%) were assisted by SUS (3.5%). Among SUS patients (30.5%), 12.9% were treated at University Hospitals (Hospital São Paulo, Puccamp, HU-USP, ABC Santo André University and Unicamp) (Table 1).

All patients treated with efalizumab (banned in Brazil since 2009) (n = 43) were not taking this medicine any longer when interviewed. Approximately 20.5% of the patients discontinued the use of biological medicines due to suspicion of adverse drug reactions which was confirmed by doctors. Adverse drug reactions included local reactions (70.0%), hospitalization after use of medicine, cardiovascular events (arrhythmia and high blood pressure), liver disease, blood dyscrasia, pneumonia, and kidney injury. The majority of the analyzed lawsuits (n = 190) did not explicitly justify the prescription of a biological medicine or provide information regarding previous treatment, evolution of the disease, supplementary exams, or diagnoses according to the ICD-10. Applicants used biological medicines for periods of more than 13 months (4.0% of the patients have been using this medicine for > 49 months), which extrapolates any follow-up of a high-quality clinical study up to this date.8,14 As for medicine discontinuation, 11.3% of the patients were discontinued because of either suspicion of an adverse drug reaction or by their own or their physician’s decision, which was always related with worsening of the condition or lack of efficacy of the medicine. Ninety-one patients were still using a biological medicine when interviewed.

Patients (n = 203) were mostly male, age ranging from 19 to 59 years, and residing in Sao Paulo. They acquired the medicine through an injunction, obtained in 7-10 days (average time). They used the prerogative of free legal aid, despite having legal representation by a private lawyer and having been assisted in private care facilities. Three private lawyers represented patients in more than 40.0% of these lawsuits filed against the state.

Instructions to obtain medicines via judicial process came from the medical doctors who assisted these patients (approximately three clinical practitioners prescribed 80.0% of requested medicines). Approximately 60.0% of patients never had a meeting with their lawyers, having signed power of attorneys at the doctor’s office. In 20.0% of lawsuits, a Non-governmental organization (patient associations) was responsible for instructing patients to request a medicine through the courts.

All patients visited their doctors once a year, but 70.3% of them visited for follow-up laboratory examinations (blood work, liver and kidney function tests), which would help them to detect possible adverse drug reactions.6

Whilst the use of biological medication for the treatment of moderate to severe PSO is considered a therapeutic breakthrough with some short-term effectiveness and tolerance,4 meta-analyses1,17 and field synopses9 advise caution in terms of long-term effectiveness and safety. National and international references5,15 recommend these medicines as a third line of action, followed by careful monitoring for early identification of adverse drug reactions.

8 Naldi L, Rzany B. Psoriasis (chronic plaque). Clin Evid (Online). 2009[cited 2014 Mar 31];2009:1706. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2907770/pdf/2009-1706.pdf
Biological medications are administered via the IV route, which can cause several local reactions, which were experienced by the patients in our study. Adverse drug reactions differ from those caused by conventional chemical compounds because they are heterogeneous and may appear years after patients discontinue their use. Adverse drug reactions resulting from 1 year of use include malignancies, opportunistic infections caused by fungi, tuberculosis, hypertension, among others. Clinical monitoring of patient, as well as of the way to use the medication, duration of use, dose, and recommendations to patients are all essential ways to reduce and control these events.

The fact that the court granted petitions containing prescriptions lacking not only relevant legal requirements (almost 100% of this study) but also important data (name of patient, name of the prescribing practitioner registered in local Regional Medical Board, date, duration of treatment, dose, generic name, among others), which are fundamental elements for proper prescribing and compulsory under current legislation, highlights the faulty drug use rationale evident in these petitions. Moreover, the situation exposes these plaintiffs to risks (disability, death) and also leads to other health issues (use of hospital beds, chronic treatments due to disability, among others) for the Health System, including direct and indirect costs.

The (i) recommendations of the Comissão Nacional de Incorporação e Tecnologias (National Committee of Technology Incorporation) of SUS; (ii) Law 12.401/2011 regarding therapeutic assistance and health technology incorporation in the scope of SUS; (iii) Decree 7.508/2011, with provisions related to planning, health assistance, and joint federal actions; and (iv) the current PCDT, do not recommend the use of these agents for the treatment of PSO. Brazilian physicians, even those working in SUS (30.5%) (Table 1), do not comply with the official recommendations and prescribe these agents to patients with PSO.

The supply of biological medicines used to treat PSO in the state of São Paulo is offered via registration of administrative requests in the Componente Especializado da Assistência Farmacêutica (CEAF – Specialized Pharmaceutical Care Program) but it does not require a proper clinical protocol follow-up of patients. After the publication of Resolution SS-54, of May 11, 2012, a Comissão de Farmacologia (Pharmacology Committee) was established in SES-SP to provide a computerized processing of administrative requests. It is the prescribing practitioner’s responsibility to justify the need for a biological medicine. However, although the above measures have favored the management of requests and granted them a technical nature (based on scientific eligibility for the use of medicines), they have not lowered the number of lawsuits requesting biological medicines.

The majority of patients with PSO (69.5%) pursue a biological medicine through the public system, but their prescription is generated by a private system. Doctors’ visits and monitoring are performed at private facilities and medicines are supplied by the public system. Patient care is not comprehensive in any of the pathways, which does not comply with the principles of SUS.

Figure. Flowchart of the phases of sample composition. State of São Paulo, 2004-2010.

---

1 Presidência da República. Lei nº 12.401, de 28 de abril de 2011. Altera a Lei nº 8.080, de 19 de setembro de 1990, para dispor sobre a assistência terapêutica e a incorporação de tecnologia em saúde no âmbito do Sistema Único de Saúde - SUS. Brasília (DF); 2011 [cited 2014 Mar 31]. Available from: http://www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/Lei/L12401.htm
2 Presidência da República. Decreto nº 7.508, de 28 de junho de 2011. Regulamenta a Lei nº 8.080, de 19 de setembro de 1990, para dispor sobre a organização do Sistema Único de Saúde - SUS, o planejamento da saúde, a assistência à saúde e a articulação interfederativa, e dá outras providências. Brasília (DF); 2011 [cited 2014 Mar 31]. Available from: http://www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/decreto/D7508.htm
3 Secretaria de Estado da Saúde de São Paulo. Resolução SS-54, de 11 de maio de 2012, Aprova, no âmbito da Fasta, estrutura e funcionamento da Comissão de Farmacologia da Secretaria de Estado da Saúde de São Paulo, e dá outras providências. Diário Oficial Estado São Paulo. 12 maio 2012;Seção 1:37. [cited 2014 Mar 31]. Available from: www.adj.org.br/download/pdf/2012/jur_resol54.pdf
### Table 1. Sociodemographic characteristics and ways used to gain access to biological medicines to treat PSO by the authors of injunction filed against the state of Sao Paulo, 2004-2010.

| Variable                                | Adalimumab | Etalizumab | Enanercept | Infliximab | Total |
|-----------------------------------------|------------|------------|------------|------------|-------|
|                                         | %          | n          | %          | n          | %     | n     | %          | n          | %          | n          |
| Gender                                  |            |            |            |            |       |       |            |            |            |            |
| Male                                    | 64.3       | 9          | 60.5       | 26         | 60.0   | 21     | 65.8       | 73          | 63.6       | 129        |
| Female                                  | 35.7       | 5          | 38.6       | 17         | 40.0   | 14     | 34.2       | 38          | 36.4       | 74         |
| City                                    |            |            |            |            |       |       |            |            |            |            |
| Sao Paulo                               | 85.7       | 12         | 46.5       | 20         | 71.4   | 25     | 58.6       | 65          | 60.1       | 122        |
| Other locations                         | 14.3       | 2          | 53.5       | 23         | 26.6   | 10     | 41.4       | 46          | 39.9       | 81         |
| Age (years)                             |            |            |            |            |       |       |            |            |            |            |
| 19 to 59                                | 57.1       | 8          | 81.4       | 35         | 74.3   | 26     | 78.4       | 87          | 76.8       | 156        |
| ≥ 60                                    | 42.9       | 6          | 18.6       | 8          | 25.7   | 9      | 21.6       | 24          | 23.2       | 47         |
| Type of medical assistance              |            |            |            |            |       |       |            |            |            |            |
| Non-SUS                                 | 92.9       | 13         | 62.8       | 27         | 65.7   | 23     | 70.3       | 78          | 69.5       | 141        |
| SUS                                     | 7.1        | 1          | 37.2       | 16         | 34.3   | 12     | 29.7       | 33          | 30.5       | 62         |
| Registered at CEAF                      |            |            |            |            |       |       |            |            |            |            |
| Information provided by the patient (Yes) | 42.9       | 6          | 65.1       | 28         | 40.0   | 14     | 51.4       | 57          | 51.7       | 105        |
| Information confirmed in the system (Yes) | 71.4       | 10         | 0.0        | 0          | 34.3   | 12     | 4.5        | 5           | 13.3       | 27         |
| Patient was being treated by a biological medicinea | 50.0       | 7          | 0.0        | 0          | 25.7   | 9      | 0.9        | 1           | 8.4        | 17         |
| Guidance to obtain a biological medicine via lawsuit |            |            |            |            |       |       |            |            |            |            |
| Doctor                                  | 71.4       | 10         | 79.1       | 34         | 80.0   | 28     | 72.1       | 80          | 74.9       | 152        |
| NGO, Family, and others                 | 14.3       | 2          | 11.6       | 5          | 34.3   | 12     | 37.0       | 41          | 6.9        | 60         |
| Lawyer                                  | 0.0        | 0          | 4.7        | 2          | 0.0    | 0      | 2.7        | 3           | 2.5        | 5          |
| Pharmaceutical Laboratory               | 7.1        | 1          | 4.7        | 2          | 0.0    | 0      | 1.8        | 2           | 2.5        | 5          |
| NI                                      | 7.1        | 1          | 0.0        | 0          | 0.0    | 0      | 0.9        | 1           | 1.0        | 2          |
| Use of biological medicine before lawsuit |            |            |            |            |       |       |            |            |            |            |
| Yes                                     | 92.9       | 13         | 93.0       | 40         | 65.7   | 23     | 95.5       | 106         | 89.7       | 182        |
| No                                      | 0.0        | 0          | 0.0        | 0          | 0.0    | 0      | 3.6        | 4           | 2.0        | 4          |
| Form of acquisition of medicine beforelawsuit |            |            |            |            |       |       |            |            |            |            |
| Pharmaceutical laboratory               | 7.1        | 1          | 6.8        | 3          | 14.3   | 5      | 0.0        | 0           | 4.4        | 9          |
| Other (city hall, State, NGO)           | 0.0        | 0          | 0.0        | 0          | 8.6    | 3      | 0.9        | 1           | 2.0        | 4          |
| Supplied by doctor                      | 0.0        | 0          | 0.0        | 0          | 5.7    | 2      | 0.0        | 0           | 1.0        | 2          |
| Own resources                           | 0.0        | 0          | 0.0        | 0          | 2.9    | 1      | 0.0        | 0           | 0.5        | 1          |
| NI                                      | 0.0        | 0          | 0.0        | 0          | 2.9    | 1      | 0.0        | 0           | 0.5        | 1          |
| Request of medication for an institutionb before filing the lawsuit |            |            |            |            |       |       |            |            |            |            |
| No                                      | 92.9       | 13         | 95.3       | 41         | 77.1   | 27     | 84.7       | 94          | 86.2       | 175        |
| No                                      | 0.0        | 0          | 0.0        | 0          | 0.0    | 0      | 2.0        | 2           | 2.0        | 4          |
| Institution activated for provision of medicine before lawsuit |            |            |            |            |       |       |            |            |            |            |
| Privatea                                | 0.0        | 0          | 0.0        | 0          | 0.0    | 0      | 5.7        | 2           | 9.0        | 10         |
| Public                                  | 7.1        | 1          | 2.3        | 1          | 17.1   | 6      | 2.7        | 3           | 5.4        | 11         |
| NGO                                     | 0.0        | 0          | 2.3        | 1          | 0.0    | 0      | 0.0        | 0           | 1.5        | 1          |
| Request fulfilled                       |            |            |            |            |       |       |            |            |            |            |
| Yes                                     | 7.1        | 1          | 0.0        | 0          | 2.9    | 1      | 1.8        | 2           | 1.5        | 3          |
| Supply of biological medication by another institution (time in months) |            |            |            |            |       |       |            |            |            |            |
| < 6                                     | 0.0        | 0          | 0.0        | 0          | 0.0    | 0      | 1.8        | 2           | 0.5        | 2          |
| > 6                                     | 7.1        | 1          | 0.0        | 0          | 2.9    | 1      | 0.0        | 0           | 0.5        | 1          |

Continue
Continuation

| Participation in a support group for patients | Yes | 14.3 | 2 | 11.6 | 5 | 17.1 | 6 | 9.0 | 10 | 11.3 | 23 |
|----------------------------------------------|-----|------|---|------|---|------|---|-----|----|------|---|
| Number of meetings with the lawyer           | None| 64.3 | 9 | 58.1 | 25 | 62.9 | 22 | 62.2 | 69 | 61.6 | 125|
|                                              | One or more | 35.7 | 5 | 34.9 | 15 | 34.3 | 12 | 37.9 | 42 | 36.5 | 74 |
|                                              | NI  | 0.0  | 0 | 7.0  | 3 | 2.9  | 1 | 0.9  | 0  | 2.5  | 4 |
| Contacted by the pharmaceutical laboratory  | Yes | 64.3 | 9 | 62.8 | 27 | 62.9 | 22 | 37.9 | 42 | 49.3 | 100|

NI: not informed; SUS: Public Health System; NGO: Non-governmental organizations; CEAF: Specialized Pharmaceutical Care Program

a Patients who were receiving a biological medicine because they were registered at CEAF.

b Any public or private institution (City hall, NGO, laboratory, and others).

c Laboratory, private hospitals.

Table 2. Features of the pharmacotherapy follow-up provided to the plaintiff. Sao Paulo, SP, Southeastern Brazil, 2004-2010.

| Variable                                      | Adalimumab | Efalizumab | Etanercept | Infliximab | Total |
|-----------------------------------------------|------------|------------|------------|------------|-------|
|                                               | %          | %          | %          | %          | %     |
| Diagnosis time                                |            |            |            |            |       |
| ≥ 6 years                                     | 6.8        | 14         | 21.2       | 43         | 6.8   |
| 2 to 5 years                                  | 85.7       | 12         | 90.7       | 39         | 85.7  |
| Up till 6 months                             | 14.3       | 2          | 9.3        | 4          | 14.3  |
| Concurrent disease                            | 0.0        | 0          | 0.0        | 0          | 0.0   |
| Treatment time with biological medicine (months) |          |            |            |            |       |
| Up to 12                                      | 35.7       | 5          | 51.2       | 22         | 35.7  |
| 13 to 48                                      | 35.7       | 5          | 48.9       | 21         | 35.7  |
| 49 to 72                                      | 28.6       | 4          | 0.0        | 0          | 28.6  |
| Average (SD)                                  | 31.4 (22.2)| 16.8 (10.2)| 26.4 (14.4)| 25.2 (14.6)| 24.0 (14.9)|
| Patient was using obtained biological medicine| Yes | 64.3 | 9 | 0.0 | 0 | 62.9 | 22 | 54.0 | 60 | 44.9 | 91 |
| Clinical monitoring a                         |           |            |            |            |       |
| Medical visit                                 | 100.0      | 9          | 0.0        | 0          | 100.0 |
| Laboratory exams                              | 55.5       | 5          | 0.0        | 0          | 68.2  |
| Reasons to discontinue the use of biological medicine |       |            |            |            |       |
| Stopped using b                               | 0.0        | 0          | 100        | 43         | 5.7   |
| Suspension by the doctor                      | 14.3       | 2          | 0.0        | 0          | 22.9  |
| Suspicion of ADR                              | 21.4       | 3          | 0.0        | 0          | 5.7   |
| Suspended by a court decision                 | 0.0        | 0          | 0.0        | 0          | 2.9   |
| Perception of the efficacy of the biological medicine |       |            |            |            |       |
| Yes                                           | 71.4       | 10         | 76.2       | 32         | 91.4  |
| No                                            | 28.6       | 4          | 21.0       | 9          | 8.6   |
| NI                                            | 0.0        | 0          | 4.7        | 2          | 0.0   |
| Perception of the evolution of the disease with the use of biological medicines |       |            |            |            |       |
| Improved/Cured                                | 57.1       | 8          | 60.5       | 26         | 71.4  |
| Stationary                                    | 28.6       | 4          | 23.3       | 10         | 20.0  |
| Worsened                                      | 14.3       | 2          | 11.7       | 5          | 2.9   |
| NI                                            | 0.0        | 0          | 4.7        | 2          | 5.7   |

NI: not informed; ADR: adverse drug reactions, SD: standard deviation

a According to recommendations of therapeutic guidelines.
b Other reasons.
| Variable | Adalimumab | Efilizumab | Etanercept | Infliximab | Total |
|----------|------------|------------|------------|------------|-------|
|          | %  | n  | %  | n  | %  | n  | %  | n  | %  | n  |       |       |
| Number of authors per injunction |   |     |   |     |   |     |   |     |   |     |   |       |       |
| 1       | 11.1 | 1  | 95.1 | 39  | 93.5 | 29  | 100.0 | 109 | 93.7 | 178 |
| 2 to 6  | 88.9 | 8  | 4.9  | 2   | 6.5  | 2   | 0.0  | 0   | 6.3  | 12  |
| Type of injunction |   |     |   |     |   |     |   |     |   |     |   |       |       |
| CI      | 88.9 | 8  | 48.8 | 20  | 58.1 | 18  | 61.5 | 67  | 59.5 | 113 |
| RO      | 11.1 | 1  | 51.2 | 21  | 41.9 | 13  | 37.5 | 41  | 40.0 | 76  |
| Public Defender | 0.0 | 0   | 0.0  | 0   | 0.0  | 0   | 0.9  | 1   | 0.5  | 1   |
| Civil Society Representation |   |     |   |     |   |     |   |     |   |     |   |       |       |
| No      | 100.0 | 9  | 51.2 | 21  | 96.8 | 30  | 92.7 | 101 | 84.7 | 161 |
| Yes     | 0.0  | 0   | 48.8 | 20  | 3.2  | 1   | 7.3  | 8   | 15.3 | 29  |
| Defendant |   |     |   |     |   |     |   |     |   |     |   |       |       |
| State   | 88.9 | 8  | 100.0 | 41  | 100.0 | 31  | 100.0 | 109 | 99.5 | 189 |
| Union   | 11.1 | 1  | 0.0  | 0   | 0.0  | 0   | 0.0  | 0   | 0.5  | 1   |
| Judicial Representation |   |     |   |     |   |     |   |     |   |     |   |       |       |
| Private | 100.0 | 9  | 48.8 | 20  | 96.8 | 30  | 92.7 | 101 | 84.2 | 160 |
| APVPESP | 0.0  | 0   | 48.8 | 20  | 3.4  | 1   | 2.8  | 3   | 12.6 | 24  |
| MP      | 0.0  | 0   | 2.4  | 1   | 0.0  | 0   | 1.8  | 2   | 1.6  | 3   |
| PD      | 0.0  | 0   | 0.0  | 0   | 0.0  | 0   | 2.8  | 3   | 1.6  | 3   |
| Free Legal Aid |   |     |   |     |   |     |   |     |   |     |   |       |       |
| Yes     | 56.6 | 5  | 75.6 | 31  | 64.5 | 20  | 75.2 | 82  | 72.6 | 138 |
| No      | 11.1 | 1  | 12.2 | 5   | 9.7  | 3   | 16.5 | 18  | 14.2 | 27  |
| NI      | 33.3 | 3  | 12.2 | 5   | 25.8 | 8   | 8.3  | 9   | 13.2 | 25  |
| Primary injunction |   |     |   |     |   |     |   |     |   |     |   |       |       |
| Yes     | 88.9 | 8  | 53.7 | 22  | 61.3 | 19  | 56.0 | 61  | 57.9 | 110 |
| No      | 11.1 | 1  | 31.7 | 13  | 25.8 | 8   | 24.4 | 32  | 28.4 | 54  |
| NI      | 0.0  | 0   | 14.6 | 6   | 12.9 | 4   | 14.7 | 16  | 13.7 | 26  |
| District injunction /Civil injunction of Sao Paulo/Osasco |   |     |   |     |   |     |   |     |   |     |   |       |       |
| 1 to 5  | 55.6 | 5  | 43.9 | 18  | 35.5 | 11  | 30.3 | 33  | 35.3 | 67  |
| 6 to 10 | 44.4 | 4  | 29.3 | 12  | 41.9 | 13  | 46.8 | 51  | 42.1 | 80  |
| 11 to 14| 0.0  | 0   | 26.8 | 11  | 22.6 | 7   | 21.1 | 23  | 21.6 | 41  |
| Osasco (1 to 2) | 0.0 | 0   | 0.0  | 0   | 0.0  | 0   | 1.8  | 2   | 1.1  | 2   |
| Legal representation of author(s) – OAB |   |     |   |     |   |     |   |     |   |     |   |       |       |
| A       | 88.9 | 8  | 48.8 | 20  | 0.0  | 0   | 55.0 | 60  | 46.3 | 88  |
| B       | 11.1 | 1  | 4.9  | 2   | 35.5 | 11  | 25.7 | 28  | 22.1 | 42  |
| C       | 0.0  | 0   | 39.0 | 16  | 22.6 | 7   | 4.6  | 5   | 14.7 | 28  |
| D       | 0.0  | 0   | 2.4  | 1   | 41.9 | 13  | 11.9 | 13  | 14.2 | 27  |
| PD      | 0.0  | 0   | 2.4  | 1   | 0.0  | 0   | 2.8  | 3   | 2.1  | 4   |
| NI      | 0.0  | 0   | 2.4  | 1   | 0.0  | 0   | 0.5  | 1   | 0.5  | 1   |

CI: court injunction; RO: ordinary proceedings; PD: Public Defender; MP: Public Prosecutor’s Office or Public Ministry; APVPESP: Association of Vitiligo and Psoriasis of the state of Sao Paulo; NI: not informed; OAB: Brazilian Bar Association; A: three lawyers had between 21 and 35 representations; B: four lawyers had between 10 and 13 representations; C: 12 lawyers had between two and seven representations; D: 22 lawyers had at least one representation per medicine.
The pharmaceutical manufacturers maintained frequent contact with more than 50.0% of patients. This suggests possible influence on patients’ needs, transforming them into legal demands.

The legal request of medicines without scientific evidence weakens pharmaceutical services because it exposes the patient to risks and promotes the financing of technologies devoid of proper proof of efficacy and safety. Efalizumab was approved for the treatment of PSO in the USA and Europe in 2003. Its marketing was suspended due to safety concerns in 2009 (three cases of progressive multifocal leukoencephalopathy), in addition to efficacy issues, rending it inferior to other biological medicines. Then, the access to this drug was obtained via lawsuits in Brazil.

### Table 4. Medical prescriptions linked to lawsuits, according to legal precepts (Law 5.991/1973): São Paulo, SP, Southeastern Brazil, 2004-2010.

| Variable                                      | Adalimumab | Efalizumab | Etanercept | Infliximab | Total |
|-----------------------------------------------|------------|------------|------------|------------|-------|
|                                               | %          | n          | %          | n          | %     |
| Legible name of author (patient)              | 4.8        | 9          | 21.7       | 41         | 15.9  |
| Author’s address (patient)                    | No         | 0          | 2.4        | 1          | 6.7   |
| Generic name                                  | No         | 100.0      | 100.0      | 41         | 30    |
| Trade name                                    | No         | 77.8       | 7          | 16         | 66.7  |
| Pharmaceutical form                           | No         | 88.9       | 8          | 100.0      | 41    |
| Concentration                                 | No         | 44.4       | 4          | 24         | 13.3  |
| Administration route                          | No         | 11.1       | 1          | 5          | 13.3  |
| Dosage                                        | No         | 11.1       | 1          | 53.7       | 22    |
| Duration of treatment                         | No         | 77.8       | 7          | 85.4       | 35    |
| Interval between doses                         | No         | 11.1       | 1          | 7.3        | 3     |
| Total quantity                                | No         | 77.8       | 7          | 85.4       | 35    |
| Name of the Doctor                            | No         | 0.0        | 0          | 2.4        | 1     |
| CRM                                           | No         | 0.0        | 0          | 0.0        | 0     |
| illegible                                     | 0.0        | 0          | 0          | 7.3        | 3     |
| Address of prescribing practitioner’s medical institution | 0.0        | 0          | 0          | 4.9        | 2     |
| Date                                          | No         | 0.0        | 0          | 4.9        | 2     |
| illegible                                     | 0.0        | 0          | 0          | 0.0        | 0     |

Source: lawsuits. Coordination of Strategic Demands of SUS (Codes). Health Department of São Paulo State. CRM: Conselho Regional de Medicina (Regional Council of Medicine)

"Presidência da República. Lei nº 5.991, de 17 de dezembro de 1973. Dispõe sobre o Controle Sanitário do Comércio de Drogas, Medicamentos, Insumos Farmacêuticos e Correlatos, e dá outras Providências. Brasília (DF); 1973 [cited 2014 Mar 31]. Available from: http://www.planalto.gov.br/ccivil_03/leis/L5991.htm"
Approximately 21.2% of patients in our study gained access to efalizumab via lawsuits deferred by the state of Sao Paulo.

Most of the interviewees were diagnosed more than six years ago. Some of the data may have suffered from recall bias. Patients who are still being treated with a biological medicine have been receiving it for more than 24 months. On the other hand, most of the data was crosschecked with the SES-SP database and with the clinical lab results provided by the patients themselves during interviews. The utilization data of biological medications were confirmed by the pharmacy from which each of the patients received these medicines.

Considering the limitations of any observational study, the results of this study may play an important role in the process of decision making in Public Health in Brazil. To the best of our knowledge, this is the first set of data on the use of biological medicines by patients with PSO financed by judicial demands in Brazil. This is important information for dermatologists, because it provides a real-life view of clinical practice, a goal that is hard to achieve with randomized controlled clinical trials.

Some treatments are associated with potentially serious adverse drug reactions. Therefore, in the long-term observational studies may provide additional and important information for doctors, users, manufacturers and researchers to assess the risks and benefits of treatments.

To perceive the public health system as one that may provide services without the requirements of in-place regulation, planning, forecasting of financial resources or epidemiological background is imprudent and can collapse the system.

The plaintiffs selected the judicial procedures to obtain biological medicines because they are either unaware of other routes or find difficulty in accessing the institutional pathways of SUS. Easy access provided by courts favors the use of biological medicines for an extended period of time through irregular prescriptions, the high frequency of adverse drug reactions and inappropriate clinical monitoring. Strict compliance to PCDT may guarantee access, effectiveness, and safety of an appropriate therapy for PSO.

REFERENCES

1. Brimhall AK, King LN, Licciardone JC, Jaéche H, Menter A. Safety and efficacy of alefacept, efalizumab, etanercept and infliximab in treating moderate to severe plaque psoriasis: a meta-analysis of randomized controlled trials. Br J Dermatol. 2008;159(2):274-85. DOI:10.1111/j.1365-2133.2008.08673.x

2. Chieffi AL, Barata RCB. Ações judiciais: estratégia da indústria farmacêutica para introdução de novos medicamentos. Rev Saude Publica. 2010;44(3):421-9. DOI:10.1590/S0034-891020100000005

3. Dommasch ED, Abuabara K, Shin DB, Nguyen J, Troxel AB, Gelfand JM. The risk of infection and malignancy with tumor necrosis factor antagonists in adults with psoriatic disease: a systematic review and meta-analysis of randomized controlled trials. J Am Acad Dermatol. 2011;64(6):1035-50. DOI:10.1016/j.jaad.2010.09.734

4. Girolomoni G, Altomare G, Ayala F, Berardesca E, Calzavara-Pinton P, Chimienti S, et al. Safety of anti-TNFα agents in the treatment of psoriasis and psoriatic arthritis. Immunopharmacol Immunotoxicol. 2012;34(4):548-60. DOI:10.3109/08923973.2011.653646

5. Hausmann OW, Seitz M, Villiger PM, Pichler WJ. The complex clinical picture of side effects to biologicals. Med Clin North Am. 2010;94(4):791-804, xi-ii. DOI:10.1016/j.mcnca.2010.03.001

6. Lopes LC, Barberato-Filho S, Costa AC, Osorio-de-Castro CGS. Uso racional de medicamentos antineoplásicos e ações judiciais no Estado de São Paulo. Rev Saude Publica. 2010;44(4):620-8. DOI:10.1590/S0034-89102010000400005

7. Lucka TC, Pathirana D, Sammam A, Bachmann F, Rosumneck S, Erdmann R, et al. Efficacy of systemic therapies for moderate-to-severe psoriasis: a systematic review and meta-analysis of long-term treatment. J Eur Acad Dermatol Venereol. 2012;26(11):1331-44. DOI:10.1111/j.1468-3083.2012.04492.x

8. Macedo EI, Lopes LC, Barberato-Filho S. Analise técnica para a tomada de decisão do fornecimento de medicamentos pela via judicial. Rev Saude Publica. 2011;45(4);706-13. DOI:10.1590/S0034-89102011005000044

9. Mazurek J, Jahnz-Rögyk K. The variety of types of adverse side effects during treatment with biological drugs. Int Rev Allergol Clin Immunol Family Med. 2012;18(1):3-40.

10. Monteiro CA, Moura EC, Jaime PC, Lucca A, Florindo AA, Figueiredo ICR, et al. Monitoramento de fatores de risco para doenças crônicas por entrevistas telefônicas. Rev Saude Publica. 2005;39(1):47-57. DOI:10.1590/S0034-89102005000100007

11. Pichler WJ. Adverse side-effects to biological agents. Allergy. 2006;61(8):912-20. DOI:10.1111/j.1398-9995.2006.01058.x

12. Rustin MHA. Long-term safety of biologics in the treatment of moderate-to-severe plaque psoriasis: review of current data. Br J Dermatol. 2012;167(Suppl 3):3-11. DOI:10.1111/j.1365-2133.2012.11208.x

13. Sánchez-Regaña M, Dilme E, Puig L, Bordax X, Carrascosa JM, Ferran M, et al. Adverse reactions during biological therapy for psoriasis: results of a survey of the Spanish Psoriasis Group. Actas Dermosifiliogr. 2010;101(2):156-63. DOI:10.1016/S1578-2190(10)70602-8
This study aimed to analyze the legal access to and usage profile of biological drugs for the treatment of psoriasis. The legal access to medications distorts planning and spending and undermines the principle of a comprehensive health care system proposed by the Brazilian Unified Health System (SUS).

A total of 203 applicants were interviewed, and 190 patients requiring biological drugs for psoriasis (adalimumab, efalizumab, etanercept, and infliximab) were examined. The patients obtained the drugs through a writ of mandamus (59.5%); without the need to request the drugs from another institution, either private or through SUS (86.2%); and using the prerogative of gratuity justice (72.6%). However, 91.1% of the patients were represented by a private attorney, 69.5% received assistance in private medical offices, and 60.0% had never met with their attorneys and therefore needed to sign proxies at the doctor’s office.

In addition, 20.5% of the patients discontinued the use of biological drugs because they reported suspected adverse reactions previously confirmed by doctors – reactions at the application site, hospitalization after medication use, cardiovascular events (arrhythmia, hypertension), liver disease, blood dyscrasia, pneumonia, renal injury, etc. Most patients discontinued the use of these drugs on their own (26.6%) or following doctor’s recommendation (13.8%) because of the worsening of the clinical status or lack of efficacy.

Important differences between clinical practice and guideline recommendations are evident in the treatment of these patients.

Professor Rita de Cássia Barradas Barata
Scientific Editor

HIGHLIGHTS

This study aimed to analyze the legal access to and usage profile of biological drugs for the treatment of psoriasis. The legal access to medications distorts planning and spending and undermines the principle of a comprehensive health care system proposed by the Brazilian Unified Health System (SUS).

A total of 203 applicants were interviewed, and 190 patients requiring biological drugs for psoriasis (adalimumab, efalizumab, etanercept, and infliximab) were examined. The patients obtained the drugs through a writ of mandamus (59.5%); without the need to request the drugs from another institution, either private or through SUS (86.2%); and using the prerogative of gratuity justice (72.6%). However, 91.1% of the patients were represented by a private attorney, 69.5% received assistance in private medical offices, and 60.0% had never met with their attorneys and therefore needed to sign proxies at the doctor’s office.

In addition, 20.5% of the patients discontinued the use of biological drugs because they reported suspected adverse reactions previously confirmed by doctors – reactions at the application site, hospitalization after medication use, cardiovascular events (arrhythmia, hypertension), liver disease, blood dyscrasia, pneumonia, renal injury, etc. Most patients discontinued the use of these drugs on their own (26.6%) or following doctor’s recommendation (13.8%) because of the worsening of the clinical status or lack of efficacy.

Important differences between clinical practice and guideline recommendations are evident in the treatment of these patients.