



III Congresso Brasileiro sobre o Uso Racional de Medicamentos

[translation of text in graphic: "Rational Use of Drugs" on button. Then "Third Brazilian Congress on the Rational Use of Drugs."]

FORTALEZA DECLARATION ON INCORPORATING THE RATIONAL USE OF DRUGS INTO PROFESSIONAL HEALTH PRACTICE

The First Brazilian Congress on the Rational Use of Drugs, held in Porto Alegre in 2005, marked the beginning of a new strategy for promoting the rational use of drugs in Brazil. The importance of this strategy was recognized by the Ministry of Health (MS), the National Health Surveillance Agency (ANVISA), and the Pan American Health Organization (PAHO), which promoted the Second Brazilian Congress on the Rational Use of Drugs, held in Florianópolis in 2007, as an institutional event. The theme of the Second Congress was “Incorporating the Rational Use of Drugs into the Brazilian Health Agenda.” Continuing in this vein, following the recommendation of the Florianópolis Declaration, the Third Brazilian Congress on the Rational Use of Drugs was held from 26 to 30 October 2009, in Fortaleza; its theme was “Incorporating the Rational Use of Drugs into Professional Health Practice.” A total of 2,012 participants attended the event, including 228 graduate students, 774 undergraduate students, and 1,010 professionals. Ten of the participants came from other countries, while 1,095 were from Ceará and 917 from other states in Brazil. The Congress’ Scientific Commission accepted 387 scientific papers from 375 educational and administrative institutions in the country and 1,151 authors. Under the theme “Incorporating the Rational Use of Drugs into Professional Health Practice,” the program addressed efforts to integrate actions advancing the rational use of drugs in Latin America, political and educational strategies on the rational use of drugs in Brazil and their impact on professional practice in health, challenges to rational access to drugs, strategies to promote the rational use of drugs in pediatrics, ethics as the foundation for the rational use of drugs, ethical aspects in the use of drugs, the interface between health and law, implementation of the rational use of drugs in the hospital environment, contributions to patient safety, working in networks, and innovative experiences in the rational use of drugs. Preceding the Congress, eight courses and four workshops addressed the topics of prescriptions, management, safety, and teaching aimed at promoting the rational use of drugs. The objectives of the discussions were to promote the sharing of experiences among professionals, managers, professors, and students in the different Brazilian regions and other countries and to foster cooperation and joint efforts on common projects. From this wealth of ideas and discussions, the participants at the Third Brazilian Congress on the Rational Use of Drugs agreed to issue the following public recommendations for consideration by various public and private entities and, in particular, by the different governance and administrative agencies of the Unified Health System (UHS) and its institutions for social accountability:

1. Promotion of the rational use of drugs should continue to be an integral and strategic part of national public policies, as the policy of the Brazilian State, in light of its multidisciplinary and intersectoral characteristics.
2. There should be recognition and formal support for the action taken by the Ministry of Health (MS), especially through its Department of Pharmaceutical Care and Strategic Supplies (SCTIE), the current management of the National Health Surveillance Agency (ANVISA), and the Pan American Health Organization (PAHO) in Brazil, particularly through its Essential Medicines and Technologies Unit. These have been fundamental to the construction of a health policy that serves the interests of the entire Brazilian population. Also fundamental were the adoption and implementation of the strategic recommendations from the workshop on “Rational Use of Drugs in a Multidisciplinary Perspective,” organized by MS/ANVISA/PAHO in 2007, as well as institutional and technical cooperation for implementing these strategies, particularly the work plan of the National Committee for Promotion of the Rational Use of Drugs.
3. There is still an urgent need to promote access to essential technologies and drugs for the peoples of the Americas, based on the principle of rational use, considering both continued innovation, the proliferation of new technologies, and the need for comprehensive, quality patient care and the financial sustainability of the Unified Health System (known as the SUS, for its Portuguese acronym) in Brazil.
4. There should be promotion of expanded debate on access to drugs and their irrational use with the institutions for social accountability in health (through consultations and conferences) and the creation of new opportunities for dialogue with society for its effective participation in building pharmaceutical services in the SUS.
5. This should include, at different levels and depending on the conditions, the promotion of rational use as a permanent multidisciplinary health care practice in the public and private sectors alike.
6. There is a need to improve communication and raise awareness about generic drugs among patients and prescribers as one of the strategies for guaranteeing access to quality drugs for the population.
7. There is a need to improve centralized procurement and management of drug inventories and strategic health supplies, and to rationalize demand and selection processes.
8. Given the difficulty of balancing finite resources, infinite needs, and rising costs, the rational use of resources should be addressed in the context of the essential drugs policy and of adopting and updating clinical protocols to rationalize prescription and health care practices.
9. The selection process should be reviewed periodically, so that the paradigm of strong evidence-based practices, with rigorous criteria of efficacy, safety, desirability, and cost

as key elements, is maintained to guide decision-making and help mitigate the irrational use of drugs (estimated at some 50% of the drugs prescribed worldwide).

10. Competition and the impartiality of the people involved in the selection should be fundamental elements of every drug selection process.
11. The children of Brazil should have access to effective drugs in age-appropriate formulations of established quality. To this end, a list of essential drugs with a specific drug formulary should be prepared. The competencies of pharmacists with respect to pediatrics and neonatology should be developed, and regulatory measures should be instituted with standards for clinical research with children in Brazil. The development and production of drugs and formulations necessary and adequate for children should be promoted in the country.
12. Appropriate drug formulations in appropriate concentrations should be included in a new edition of the National Report on Essential Drugs (RENAME), as well as drugs specifically for the clinical care of children and the elderly.
13. International, national, state, municipal and institutional lists should be consistent with each other, using a cascade process and taking advantage of the respective expertise of the different groups producing these lists.
14. A planned policy for the integration of Ministry of Health programs should be established, so that drug selection lists are considered documents for guiding other actions that are part of drug policy (preparation of drug formularies, clinical guidelines, manufacture of drugs, training of professionals, etc.).
15. Lists and additions to lists should be widely distributed and disseminated in the country, facilitating broad access to the information by all professionals, so that managers and professionals can fully assimilate the concept of essential drugs into their practice, contributing to the generalization and internalization of the paradigm of evidence-based conduct in health practice.
16. Health professionals should be trained in critical analysis of the validity of scientific information (reliable evidence) and in avoiding conflicts of interests.
17. Ethics, in the sense of a lack of conflict of interests, should permeate the therapeutic decision-making process, from professional education through patient care.
18. Individual and collective values should be encouraged to avoid the use of untested drugs, medicalization (invented diseases), and promises of miraculous drug cures.
19. Tackling growing litigation over the right to health requires responding to all the demands to enforce SUS directives, emphasizing the importance of matching supply with demand, from the selection process through the dispensing of drugs and the use of health technologies.

20. Considering the influence of advertising and publicity, which leads to the creation of health needs and new market niches for “marketed” diseases, there is need to raise awareness about good prescribing practices based on “conservative prescribing principles,” eliminating the practice of innovation based essentially on commercial interests.
21. Unrestricted advertising of drugs to consumers should be limited, making the primary marketing perspective one of providing the information needed for users to understand what is being marketed.
22. Hospitals, chiefly those that are public or receive government incentives, should bar pharmaceutical industry advertising to students and staff, as well as the donation of drugs, often in insufficient quantity, for use in the hospital
23. Hospitals should buttress the role of the hospital physician, with the following benefits: lower turnover of physicians in the hospital, allowing for greater integration with all the services and other professionals, and fostering teamwork; greater skill building, which will improve emergency care, reducing mortality and morbidity; promotion of shorter hospital stays for patients, with the advantage of reduced morbidity (hospital infections, deep vein thrombosis) and lower costs; better information for patients and their families or caretakers, resulting in lower post-hospital morbidity.
24. The rational use of drugs should be widely promoted as good professional practice in dentistry, considering the oral surgeon as a prescriber and a health professional involved in multidisciplinary care.
25. The rational use of drugs policy should be used for prioritizing primary health care (PHC) activities, understanding PHC as the gateway to the health system, and the family health strategy as the structural core of this system. In this context, one should consider the renewed primary health care strategy of PAHO/WHO, which puts the patient at the center of the health care scenario. One should also note that drugs are one of the leading components of access to health in the global context, where 80% of the population has access to only some 20% of the world pharmaceutical market.
26. The Family Health Support Unit (NASF) should contribute to the training of community health workers in aspects linked to the rational use of drugs, encouraging prescribing based on protocols selected or established by pharmacy and treatment commissions in the coverage area, with components of the family health teams.
27. In order to discern health needs in Brazil, there should be a national survey to collect information on the disease profile, to assist in setting up an incentives program for the production of essential drugs, especially in appropriate formulations for rational use, and prioritizing the policy for providing incentives for the production of essential drugs, including pediatric dosage forms.

28. There should be an agenda for discussions between the State and civil society, based on the concept of health interests, on the drug registry and its incorporation into professional practice.
29. Brazil should make use of existing safeguards to guarantee that “patent rights” do not impede access by the population to drugs and technologies deemed necessary and strategic, by strengthening the use of the prior authorization instrument for the concession of patents for drugs and pharmaceutical processes.
30. Access to registry information on clinical indications for essential drugs should be available from ANVISA in order to prevent off-label use.
31. Studies of pharmaceutical economics should be conducted and disseminated.
32. Drug surveillance, which plays an important role in decision-making on the use of drugs at different health care levels, should be incorporated into professional practice, laying the foundation for health programs and policies to promote the rational use of drugs.
33. The Drug Information Centers and Services should be formally incorporated into the National Health Policy, a need already identified in several legal documents dealing with the rational use of these technologies.
34. There should be a national policy on toxicology services that includes the Toxicology Information and Services Centers in the national health policy.
35. Whereas article 4.5 of the National Policy on Health Care for Indigenous Peoples(PNASPI–Ministerial Directive No. 254/2002/MS) states that promotion of the appropriate and rational use of drugs is one of its guiding principles, and must conform to the National Drug Policy and the National Pharmaceutical Policy; whereas the responsibility for activities at the national level lies with the Unified Health System (SUS), through its Indigenous Health System, as stated in Law No. 8.080/1990, articles 9, 15, and 16, and the management of health care for indigenous peoples is the responsibility of MS/FUNASA, as well as the States and Municípios with these communities in their territories, the following are recommended:
 - the decentralization of pharmaceutical care management in the areas of the 34 Special Indigenous Health Districts (DSEI), pursuant to the guidelines in article 4.5 of PNASPI;
 - resumption of the activities of the National Committee for Pharmaceutical and Health Care of the Indigenous Population, laid out in Ministerial Directive No. 1,057/2006/FUNASA, which establishes as a priority goal the preparation of a directory of essential drugs for indigenous communities, based on the National Report on Essential Drugs (RENAME);
 - training for indigenous staff and communities in promotion of the rational use of drugs.

36. Using appropriate strategies, the assessment of the rational use of drugs in the country should be shared with professional entities, such as unions and professional boards and associations in medicine, dentistry, pharmacy, nursing, etc.
37. Dissemination and promotion of the Rational Use of Drugs (RUD) in Brazil should continue as a permanent responsibility of the State.
38. Joint Latin American activities for RUD should be strengthened. For example, Brazil's participation in networks such as DURG-LA and other Latin American activities that advance the rational use of drugs should be intensified.
39. A national drug bulletin should be created, with a periodicity and quality that will permit its inclusion in the International Society of Drug Bulletins (ISDB)
40. Drugs should be considered health benefits rather than consumer goods in the context of the social right to health, and incentives for healthy practices should be encouraged as an alternative to drug therapy. Incentives to encourage exercise, a healthy diet, and social contacts can be effective in controlling and preventing chronic diseases such as hypertension and diabetes.
41. Relations between health professionals and patients that promote respect for patients' rights and sharing of the common objective of preserving patient health should be encouraged.
42. Considering Brazilian experiences with the inclusion of RUD as a subject for teaching and research and dissemination to society, there is a need to consolidate and expand the opportunities and incentives for such activities in the following ways:
 - a. Promotion of the rational use of drugs should be a cross-cutting subject in undergraduate and graduate health education, especially in courses that deal with the prescription of drugs, such as medicine and dentistry, as well as pharmacy and nursing;
 - b. Legal and ethical mechanisms should be found to prevent drug advertising from influencing professional learning scenarios and strategies;
 - c. Information independent of commercial interests should be produced and made widely available to health professionals and society;
 - d. There should be broad strategies for widening the debate in Brazilian society on the role of drugs in health care and other commercial strategies;
 - e. Indicators should be established for assessing the impact of the action taken to promote RUD in the practices of the health services;

- f. Educators should be made aware of and motivated to work toward the rational use of drugs, employing active methodologies and cooperating with health professionals, integrating teaching and service with a multidisciplinary approach throughout the training period;
 - g. Existing programs, including Pro-Saúde, the Tutorial Education Program (PET), Family Health Strategy Program (NASF), the Institutional Program for Introductory Science Scholarships (PIBIC), and multidisciplinary residencies should be strengthened, with the subject of RUD more explicitly defined;
 - h. Results from the training courses for RUD and evidence-based health sponsored by ANVISA and Ministry of Health should be evaluated and ways to provide continuity proposed;
 - i. Specific efforts should be made to ensure that meetings on RUD are called in such a way as to involve the entire health team;
 - j. Encourage health research on RUD through interdisciplinary proposals involving professionals from the health services, university educators, and undergraduate and graduate students in daily instructional activities;
 - k. Professional training for the promotion of RUD should use distance learning websites and courses; this is particularly relevant and cost-effective in a country the size of Brazil.
43. The knowledge amassed by Brazil over three successive Congresses on the Rational Use of Drugs should be disseminated more widely, lending greater visibility to the issues discussed, sharing insights with the countries of the Region of the Americas, and putting the event within a regional perspective. Alternatively, a Latin American and Brazilian event could be held, with the support of international institutions and organizations.

Fortaleza, Ceará, 30 October 2009, 120th year of the Republic; 32nd year since the publication of the first List of Essential Drugs; 31st year since the Alma-Ata Conference; and 24th year since the Nairobi Conference on the Rational Use of Drugs. Declaration approved by acclamation at the closing session of the Third Brazilian Congress on the Rational Use of Drugs.