

## Essential medicines and technology incorporation following novel Brazilian Public Health System regulations

Novos delineamentos da Assistência Farmacêutica frente à regulamentação da *Lei Orgânica da Saúde*

Nuevos planteamientos de asistencia farmacéutica frente a la regulación de la *Ley Orgánica de Salud*

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In Brazil, *Law 12,401* of April 2011 <sup>1</sup> and *Decree 7,508* of June 2011 <sup>2</sup> introduced amendments and additions to *Law 8,080* of 1990, pertaining to patient care and the incorporation of technologies by the Brazilian Unified National Health System (SUS) and intended to contribute to the implementation of comprehensive care. However, the new legislation appears to have perpetuated the discussions and disagreements on the underlying concepts, guidelines, and principles of comprehensiveness.

The public health experts that formulated SUS suggested “regulated comprehensiveness” based on ethical, scientific, and social premises <sup>3</sup> for establishing equitable access and guaranteeing individual rights in keeping with the population’s health needs.

Recent years have witnessed the consecutive enactment and repeal of various rulings and provisions and the realignment of activities in Pharmaceutical Services. Comprehensiveness based on regulations and distinct forms of financing and organization of access have produced greater fragmentation of Pharmaceutical Services, distorted by demand issues and prioritizing the interests of the country’s various States, to the detriment of benefits for the citizenry.

*Decree 7,508* introduces some prominent measures. These include the National List of Health Actions and Services (RENASES), encom-

passing all the actions and services supplied by the SUS and specifically defining their scope through continuously updated lists of services and actions. The Decree provides that the user receive a prescription issued by the SUS according to the National List of Essential Medicines (RENAME) and the Clinical Protocols and Treatment Guidelines (PCDT). The medicines are dispensed exclusively within units of the SUS <sup>2</sup>, thereby limiting the scope of comprehensiveness to the performance of all stages of care within SUS. Meanwhile, the difficulties in provision of medium- and high-complexity care are well-known; in addition, the incorporation of technologies per se, without articulated action between the hierarchical levels, has a limited impact in terms of improving access <sup>4</sup>.

In this context, the configuration of the RENAME is a central point in the debate. Lists of essential medicines have been adopted worldwide, elaborated according to the concept of essential medicines proposed by the World Health Organization (WHO) since 1977. Such lists are the key to all administration of Pharmaceutical Services. They provide the structural basis for other actions, such as forecasting, organization of financing, procurement, logistics, and the actual use of medicines. Since 1997, Brazil had been formulating an evidence-based list of essential medicines according to the National

Medicines Policy (PNM) and the National Policy for Pharmaceutical Care (PNAF). The penultimate versions of the RENAME (2000, 2002, 2006, 2008, and 2010) were developed on the basis of a comparative evaluation of efficacy, effectiveness, safety, convenience, and cost of medicines for the country's priority health conditions. These editions contained an average of 350 medicines. The RENAME included medicines for low, medium, and high complexity of care that represented the best options for first and second line treatments. The list was also an important management tool, and it was recommended for adoption and possible adaptation and/or complementation by States or Municipalities concerned with providing the best possible pharmaceutical services for their inhabitants.

However, the RENAME list recently re-emerged with a completely reformulated concept and composition. *Ministry of Health Ruling 533* of March 28, 2012<sup>5</sup> redefines it as a single list comprising the components of financing of pharmaceutical services (combining all the items from all the Ministry of Health's programs and actions, many of which were not evidence-based), totaling 810 items, all of which were termed as "essential" by the Ruling.

This type of list is subject to constant stress, both by pressure from the growing market of new health technologies and political opportunities for supplying medicines that are frequently the object of court cases, with a dubious risk/benefit profile. This scenario was already visible in the States and Municipalities when the wave of individual court cases began to fuel the acritical addition of technologies to government funded lists<sup>6</sup>. From the public health point of view, none of these factors legitimizes the hasty or abusive incorporation of medicines by SUS.

The National Commission on the Incorporation of Technologies by the National Health System (CONITEC) was created by *Law 12,401* and has been in operation since mid-2012. As of February 27, 2013, the Commission had received 114 petitions for the inclusion or expansion of technologies by the National Health System. As of that

date, the Commission had issued 30 rulings and incorporated 30 medicines (CONITEC. [http://portal.saude.gov.br/portal/saude/Gestor/area.cfm?id\\_area=1611](http://portal.saude.gov.br/portal/saude/Gestor/area.cfm?id_area=1611), accessed on 28/Feb/2013). As far as we could ascertain, there have been no efforts to review the 810 medicines in the current "RENAME" list, many of which are inappropriate for supply by the SUS.

Considering that States already experienced difficulty in managing a list of 350 essential medicines, the 810 medicines in the new "RENAME" list (plus those that will likely be added in the future) will prove even more problematic. Given the pace of incorporation of new technologies (many of them high-cost), it is important to emphasize that when SUS defends the principle of comprehensiveness in pharmaceutical services, the system should safeguard its own long-term sustainability. It is necessary to adopt a single list of essential medicines based on evidence and legitimized by national needs, adhered to by prescribers and health managers and acknowledged by the population as effective, in contrast to the positive list for financing, consisting of various new technologies and medicines that fail to meet the definition of essentiality.

The adoption of an amalgam of countless government funded lists (like the current "RENAME" list) that have appeared and taken hold in recent years represents a step backward, fostering the logic of financed supply as a substitute for the logic of priority-based needs.

Comprehensiveness can still be a useful and ethical concept for identifying desirable values and characteristics for the health system<sup>7</sup>, as long as it refers to access by all citizens to low-, medium-, and high-complexity procedures and pharmaceuticals and health products. Such access should not be ensured merely by political convenience, but through a socially negotiated process. It is urgent to revise the concept of comprehensiveness currently permeating Pharmaceutical services and SUS, since it has materialized and perpetuated itself not as a virtuous principle, but as a problem running contrary to the population's health priorities.

### Contributors

C. D. B. Santos-Pinto contributed to the conceptualization of the theme, the literature review, and the writing and revision of the article. M. Ventura and V. L. E. Pepe contributed to the writing and revision of the article. C. G. S. Osorio-de-Castro contributed to the conceptualization of the theme and writing and revision of the article.

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Submitted on 06/Mar/2013

Approved on 27/Mar/2013