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Uncertain future for essential medicines in Brazilian Unified National Health System

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Essential medicines are those used to treat a population's priority health needs. Brazilian National Policy of Medicines (PNM), launched in 1998, uses the *National List of Essential Medicines* (RENAME) as its primary guideline and underlying framework. RENAME is the backbone of the National Policy of Medicines. All efforts in the development, regulation, production, supply, and utilization of essential medicines should be based on the list.

Policies have been developed over time to offset phenomena caused by supply shortages and pressures from innovation and the market, meanwhile deeply reconfiguring the RENAME. Figueiredo et al. [1] discussed the incoherencies of the "new RENAME" in an article in 2014, showing that starting in 2012, various arbitrary measures disfigured the list, depleting it in several major therapeutic classes such as cancer drugs, while hypertrophying it in relation with other national health priorities, all appropriately represented by burden of disease [2].

Production by public laboratories is another guideline of the PNM. The policy specifically calls for "*effective linkage between activities in the production of medicines listed in the RENAME*" and highlights the need for mechanisms to "eliminate dependency" and "achieve levels of competitiveness" in public laboratories. With the difficulties these laboratories have experienced in reaching these objectives alone, other strategies have gained momentum over time, including Industrial Development Partnerships (PDPs in the Portuguese acronym). Such partnerships are a form of industrial technology transfer, or transfer of the associated technological knowledge and inputs produced, operating as an agreement between the holder of the technology, normally belonging to the private sector, and the public laboratory [3]. However, the implementation of PDPs is based on the establishment of a "strategic" list, an umbrella arrangement, adding drugs (representing various medicines in different pharmaceutical forms and concentrations) that are priorities for the Brazilian Unified National Health System (SUS) and those that are strategic to the Industrial Development Partnership, as strategic lists for public production.

The new article by Figueiredo et al., entitled *The Public Production of Medicines Compared to the National Policy of Medicines and the Burden of Disease in Brazil* and published in this issue, provides an expert discussion of the issue. The article addresses the mismatch between the strategic list (versions 2013 and 2014), the laboratories' lists, and the 2014

RENAME. Only 25 drugs coincided on all three lists. The authors go on to show that although the strategic list "gravitates" towards the most expensive products, mostly cancer drugs, inexplicably absent from the RENAME since 2012, it also includes (incomprehensively) drugs that are present in the Basic Component of Pharmaceutical Services, frequent in the production by official laboratories, the provision of which the system already guarantees. Other important priorities identified by burden of disease [2] are not covered by products from the strategic lists of 2013 and 2014. The authors cite drugs from these lists in relation to the population's health needs, based on burden of disease, thereby calling attention to the urgent need to define criteria for composing the strategic list and priorities for public production, with consequences for the sustainability of provision within the SUS.

The authors' analysis is extremely useful and spawns new reflection by comparing the new strategic list for PDPs published in Ministry of Health *Ruling 252* of January 2017 [4] with the RENAME from 2014, prevailing as of publication, and that of 2017. Of the 52 products on the strategic list for 2017, one is a diagnostic test and four are cancer drugs. Of the 47 other drugs, singly or in association, 22 were absent from the 2014 RENAME. Compared to the 2017 RENAME, the number dropped to 16. Two issues stand out if one assumes that the RENAME should make available to the SUS all the products with evidence of efficacy, safety, effectiveness, and cost-effectiveness: there are drugs on the strategic lists that do not appear in the successive editions of the RENAME. They were not incorporated by the system, even though they had been on the strategic list for more than three years. Meanwhile, since *Ruling 252* was issued, medicines included on the strategic list, like insulin analogs, have been incorporated by the SUS and are listed in the RENAME. It thus appears that being on the strategic list may increase the drug's odds of being incorporated by the SUS.

All this raises several questions: which drugs are actually included on the strategic list for the SUS? Those that meet health priorities? Or that should be incorporated and listed in future RENAMEs? Those that are on the technological horizon? Those that are purchased but not incorporated by the SUS? The most expensive ones, or the ones patients only obtain by taking legal action? Those that lack consensus concerning their relevance to health priorities, or that lack evidence of effectiveness and cost-effectiveness from the perspective of the SUS, but which attract industry's interest? Which factors determine incorporation, inclusion on the RENAME, and inclusion on the strategic list for the SUS?

These questions expose obvious and repeated incoherencies that run counter to the proposals of the PNM. There are characteristics that help "policy", a formal aggregate of government/state intentions, to overcome arbitrary approaches and take shape as Policy "with a capital P": the continuity and internal coherence of various plans, programs, and actions over time. It is reasonable to assume that the more coherent and lasting a policy, the more fruits it will bear.

However, the RENAME, which should be the backbone of the PNM, representing the system's supply to the population and influencing all the other actions and services, as well as other policies that intersect with the policy for medicines, appears to no longer fulfill its role. External pressures have produced a deformed RENAME and a parallel, "strategic" list whose composition is subject to other, opaque determinants.

We have asked ourselves repeatedly, given the crisis gripping Brazil: where is the SUS headed? The future may hold other surprises for us, but we can already glimpse an uncertain future for essential medicines in health sector actions and policies, as in the case of the PNM.

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