



Freeing ourselves from regulatory imperialism: A sanitary democracy manifesto

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Countries around the world are struggling to adequately monitor the quality of medicines available to their citizens. From more regular manufacturing inspections, to risk based investigations into the sourcing of ingredients, to a rethinking of post-marketing surveillance (pharmacovigilance), there isn't one single solution—and efforts to reach international “harmonisation” are part of the problem.

Advising and training countries with severely under-resourced medicines regulatory agencies to adopt the standards and practices of the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA) is unrealistic at best and, at worst, dangerous. Indeed, it often results in the cutting and pasting of

western rules and guidance to satisfy international institutions taking the place of real advances in quality and safety oversight. We must strive to free ourselves from the bonds of “regulatory imperialism.”

What we need are programmes for “sanitary democracy” that recognise the situation as it exists, and provide both a path for convergence with global best practices and immediate tactical programmes that can address the true situation on the ground. Rather than Potemkin pharmacovigilance, sanitary democracy strives to manage what already exists rather than undertaking a full scale systems redesign. In brief, sanitary democracy is tactical, pragmatic regulation that recognises

the asymmetries inherent in an evolving regulatory ecosystem.

Public health must be a forum, not just a database. Sanitary democracy puts the patient physically (phenotypically) at the centre of the post-marketing surveillance system.

Sanitary democracy is an expedited pathway for pharmacovigilance that embraces a philosophy of multi-variant inputs and the potential leapfrog impact of technologies, such as mobile apps and artificial intelligence opportunities, which result in shortening the reporting to action continuum. Artificial intelligence will facilitate what the pharmacovigilance ecosystem lacks today: a coordinated and efficient system for developing actionable evidence on safety and effectiveness.

Today, the absence of these capabilities significantly impacts public health by creating obstacles to patients and clinicians receiving the meaningful information they need to make informed decisions. This perpetuates unnecessarily long delays and gaps in effective and timely safety communications and recall management, hinders the timely development of new and innovative treatment options, and increases the overall costs and inefficiency of the healthcare system.

Sanitary democracy means collaborative programmes that enhance communications between regulatory agencies and physicians, hospitals, pharmacists, and patients so that we can encourage more timely post-marketing reports of both adverse events and substandard

pharmaceutical outcomes. In an ideal world, this would require national efforts to establish a network of electronic health records, but we do not live in an ideal world. In the real world, it must mean using any means available from mobile apps to traditional paper reporting. Leadership and collaboration equals speed to action.

Sanitary democracy understands that the perfect mustn't get in the way of the good. In fact, "good" is a highly worthwhile goal. "Good" recognises the need for continuous improvement. Data from every source is important, but is not necessarily equal. Which are the "signals" and which the "noise?" Rather than letting this important question stymie progress, sanitary democracy suggests a more tactical, risk based decision making process that ranks information, by source, on a reliability scale. Such a strategy recognises the inherent inconsistency of quality reporting, while also understanding the value of quantity as a predictive tool.

Does this mean the death of classic pharmacoepidemiology (PEPI)? Certainly not, but PEPI must be understood to be a tool—not a strategy. Today, unfortunately, PEPI can be a tactic for delaying regulatory action (by manufacturers) and a cause for delay by regulators (due to insufficient staffing and expertise to collect and review data). These are decidedly undemocratic consequences.

Sanitary democracy recognises the importance of not only acting faster based on imperfect evidence, but also understanding the real world impact

those actions have on both the lives of patients and (more broadly) the quality of medicines within any nation's borders. In order to succeed, sanitary democracy must be both pragmatic and evolutionary. That is why at the very heart of sanitary democracy doctrine is the belief that the best way to avoid questionable data is to question the data.

Sanitary democracy also believes in the power of predictive evidence, but also in understanding that the lack of post-marketing reports must also be a cause for concern. The lack of signals is an important signal to take into regulatory consideration. This requires regular monitoring of other reporting sources (via bilateral national information sharing) and international repositories, such as the World Health Organization's Uppsala database for global adverse event reporting.

The world's greatest chess players understand that every variable

(analytic, contextual, social) is interdependent and relevant. Sanitary democracy means creative intelligence for impact. It means smarter ways of utilising existing intelligence in order to achieve enhanced public health for patients faster.

Sanitary democracy frees developing nations from the bondage of regulatory systems developed for advanced needs. Lockstep harmonisation with "best western practices" is likely pointless, considering the profound differences in regulatory staffing levels; overall budgetary limitations; and physician, pharmacist, and patient education.

Expecting other nations with less experience and resources to "harmonise" with the FDA or the EMA isn't the right approach. Just as every nation has its own unique culture and cuisine, so too must countries design their own pharmacovigilance philosophy and structure.

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