Original Article

Public–private partnerships in addressing counterfeit medicines: The development of the Partnership for Safe Medicines and the Partnership for Safe Medicines-India

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ABSTRACT **The global drug supply chain has resulted in tremendous vulnerabilities. Despite individual country efforts, both developed and resource-poor countries have experienced tremendous challenges with ensuring safety of the drug supply. In this piece, the formation of a novel public–private partnership (PPP), the Partnership for Safe Medicines (PSM), is described to illustrate the issues involved in creation of a successful stakeholder-based PPP. It then expands this discussion to the unique concerns when establishing global PPPs, describing the formation of the PSM-India. The formation of these partnerships may guide future efforts to create PPPs to address other public health and patient safety issues.**

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INTRODUCTION

Public–private partnerships (PPPs) are being utilized in almost every industry sector across the globe.[1] But nowhere are PPPs as critical as in the global fight to curb counterfeit medicines. This problem is so pervasive, so broad and so global[2] that we cannot even begin to address it without sincere collaboration among every stakeholder across all continents.

With this as a baseline, planning efforts were made to involve public and private stakeholders. This culminated in 2003 when the Partnership for Safe Medicines (PSM) was formed. Below I describe PSM, its structure and its initiatives that may promote understanding and greater key collaborative, strategic relationships that can create effective PPPs. Further, I detail efforts to establish an

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international partnership, the PSM-India, for additional details on international collaborations.

PSM

PSM is now a coalition of more than 65 organizations dedicated to the safety of prescription drugs and protecting consumers against counterfeit, substandard or otherwise unsafe medicines. A key focus was to identify and create a substantive partnership of stakeholders focused on public health concerns with regard to the global safety of the drug supply, and avoid simply calling the group a partnership in name only. Critically, this meant identifying a core mission and set of principles to then creating untraditional alliances between parties that may otherwise conflict in their business activities. However, our belief was that an emphasis on the commonality of the public health mission could integrate disparate stakeholders into a successful partnership.

Fortunately, with this foundational approach, PSM has created a partnership in the truest sense of the word. First, we identified core principles for all members of PSM:

1. counterfeit drugs do exist;
2. they are not safe;
3. consumers can take action to avoid them, even with the sophisticated efforts counterfeiters are taking to defraud the consumer.

These principles drive PSM's unifying mission to protect the supply chain, regulate online sellers and unify globally in the fight against counterfeit drugs.

Identifying this core set of principles then led to recruitment of partners. By limiting this core set to a public health and patient safety focus, a broader set of potential partners could be amenable to joining.

This approach succeeded quite well. The breadth and depth of members that have joined PSM represent the full range of industries and advocacy organizations with a common, vested interest in safe drugs. For example, PSM has both branded and generic pharmaceutical manufacturers (that is, the Pharmaceutical Research and Manufacturers of America and the Generic Pharmaceutical Association), patient groups (such as the ALS Association and the National Alliance on Mental Illness), pharmacists (like the National Community Pharmacists Association and the American Pharmacists Association), academics (including the University of Texas College of Pharmacy and the Institute of Health Law Studies at California Western School of Law) and leaders in the global fight against counterfeit drugs (such as the National Association of Boards of Pharmacy and International Anti-Counterfeiting Coalition), just to name a handful.[3]

CONTINUING EFFORTS FOR PSM IMPACT

Supportive materials

As a global public health and patient safety partnership, PSM recognized that to have impact on global drug safety, the partnership needed to fill in informational and skill vacuums in professional and lay settings. Hence, creation of useful, supportive materials was a priority for PSM. We also believed that to ensure use in resource-poor settings, all materials should be available for free.

PSM has therefore created a large set of materials supporting its mission. These include free resources for patients, pharmacists, providers and policymakers through the PSM web site, www.safemedicines.org. For informational needs, PSM compiles the latest news and data on counterfeit medicines to blast to our membership and e-mail lists. This information is also disseminated through web-based weekly newsletters and PSM member organization distributions.

Further, in partnership with the US Food and Drug Administration and other drug regulatory authorities around the globe, PSM has its SafeMeds Alert system, which actively warns consumers regarding drug safety concerns issued by governments. Additionally,

again to maximize use and impact, we are constantly updating and adding to resource guides we have created to assist consumers and health-care professionals avoid, identify and report fake medicines. At present, PSM resources are available in five languages – English, Spanish, Chinese, Vietnamese and Taglog.

Annual conference

Beyond PSM individual communications with members that have led to fruitful projects, PSM noted that a forum for member communication as well as broader community participation could leverage important core messages and PSM-created tools while potentially increasing visibility to this problem. Hence, in 2010, PSM held its inaugural Interchange Conference, where we brought together key constituencies for a full day dialogue on the fight against counterfeit drugs and where opportunities and challenges exist.

The event exceeded all expectations, with more than 100 attendees and a keynote address from US FDA Commissioner Dr Margaret Hamburg. By creating an annual conference, PSM convened one of the first events in the United States to bring all stakeholders together in one room to listen, learn and share information so as to work together to meet the goal of keeping our global drug supply chain safe. Given the overwhelming positive response, relationships begun and policymaking inroads made, PSM will hold this event annually.

PSM-INDIA

Given the global nature of the drug supply chain, working solely within US borders would be like sticking a finger in a dam. Safety in this regard requires coordination internationally and with great regularity. As such, PSM believed that other, sister partnerships needed to be created to most effectively promote safety. Because PSM was successful in the United States, we believed we could apply PPP principles in other countries.

Creating PSM-India: Tailored principles

I should emphasize that this was by no means a turnkey operation. It took years of preparation, planning and research to develop a framework that could be customized for each country without compromising the overall goals of PSM's efforts.

We began by building on PSM's core principles to develop a document to serve as the driving tenets for affiliate organizations in other countries. Again, a focus on short, clear, uncomplicated goals was emphasized to avoid disagreement and dissension leading to fracture and failure. In addition, at a high level, the domestic and international principles are the same, we provided additional explanation and guidance to give each country the flexibility to focus on the aspects of unsafe medicines that are most urgent for the health of its citizens.

What was most interesting in this process was discovering the necessity of tailoring the objectives of a new PSM entity depending on the country. In the United States, our primary concern is counterfeit medicines infiltrating our closed drug supply chain. In India, the focus is more around pharmacovigilance and post-market surveillance; by comparison, in South Africa for example, the primary concern is the safe use of medicines given the low literacy levels in the country. It would spell failure to require international PSM affiliates to strictly adhere to the objectives of the US PSM without acknowledging the realities of each country.

PSM-India: Partnership tool kit

Along with the international principles, we developed a comprehensive tool kit for those interesting in starting a partnership in a selected country. This includes a brief eight-step checklist to begin an affiliate, but most importantly includes a matrix for success, as well as a cost-sharing mechanism.

Importantly, PSM avoided simply handing the checklist over to an interested person within a country and hope for the best. But the ultimate goal of a PSM outside

the United States is to make progress and ensure the international affiliates are successful, sustainable and self-sufficient. To do so, we also created a benchmark matrix, which outlines key milestones and goals, a suggested timetable for completion, and a requirement for reporting progress. This keeps the in-country leads on target while keeping the US PSM informed of progress and roadblocks to allow rapid assistance if necessary. Importantly, the US PSM also contributes through providing developed best practices that would allow for quick corrections when efforts may run off course in a country.

PSM-India: Cost sharing

PSM offers some limited cost sharing with interested countries who wish to set up their own PSM. From one perspective, a cost-sharing mechanism is the most important element for creating viable PSMs in other countries that substantively represent a network of affiliates with autonomy to be effective in-country while collaborating together at a global level to keep medicines safe. Key to this goal is creating affiliates that are self-sufficient from a funding perspective. That creates credibility for the organization and a sense of ownership for those involved. Simply put, if it is built in India, it must be Indian centric. The cost-sharing ratios for each country will differ, but all will have the same goal – to be wholly funded in country in 5 years' time. Each affiliate must achieve predetermined milestones before funding from the partnership is provided, and we will work with them to create a fundraising plan and program.

Indeed, it is PSM's strong belief each international affiliate must be developed organically from within the country's borders. PSM can help assist with the process, but the clear necessary condition is that success will only occur with investment and ownership from within the targeted country. The benchmarks and cost-sharing system are the best ways to ensure that happens – and ultimately ensure success.

PSM-India: Executive director/ leadership

One of the most challenging aspects to creating a PSM affiliate is the identification of an executive director, the in-country champion that will lead the public health and patient safety effort. The individual must possess the greatest sense of balance, respect and understanding for the issues that impact patients in this area, always keeping in mind the concerns of the multi-stakeholder population they represent. This is no easy task and as we at PSM well know from prior efforts around the globe, if the correct and best-suited individual is found early in the process, the organization will often take care of itself in the long term. Hence, significant time and effort must be taken to identify and recruit this person.

Experiences with setting up PSM-India have shown the value of this approach. To begin, members of the PSM board of directors and I traveled to India close to half a dozen times to conduct more than 50 meetings with key stakeholders in Delhi and Mumbai over a 2-year period. These meetings involved guidance from long-term drug safety advocates in India, Government of India officials, representatives from US FDA in India, patient advocacy organizations providing care and support to children suffering from cancer, and industry of all types, to name a few. These meetings gave us a strong sense of the core issues in India, who the most active stakeholders were, and helped us identify what we needed to look for in an effective executive director. PSM representatives actually met PSM-India's future founder and executive director, Mr Bejon Misra, on one of our first visits but did not realize that he was the perfect candidate until 2 years later.

Through these initial meetings and, subsequently, with Mr Misra's guidance and reputation, we were able to obtain buy-in from the key stakeholders in India to support creation of a PSM affiliate within the country. This included the same type of groups as PSM in the United States: consumer groups,

physicians and providers, pharmacists, patient groups, industry and government officials. Additionally, these stakeholders were essential in assisting the drafting of key India-specific objectives for PSM-India, which include integration of spurious with counterfeit, substandard and unsafe medicines, involvement of all the stakeholders in an equitable manner, learning from modern technology from around the world to empower and enable Indian consumers to access safe medicines at the most affordable price, ensuring consumer safety prevails profit, and targeting the poor and vulnerable consumers in developing countries.

PSM-India: Addressing conflict issues

Extremely important to PSM India's success was the clear outline at the outset that spurious drugs were the focus and not the very contentious intellectual property (IP) debates that have become conflated around the globe. Again, the theme of focusing on public health and patient safety aspects of the problem was essential for participation. Parties historically arguing with one another about IP ssues such as patents and data protection agreed to set those issues aside and focus on the fundamentals: the quality and safety of the product taken by the patient. Those debates will still exist, but in this case, all parties were able to agree to keep their attention on the most important entity: the patient.

PSM-India: Launch

Following years of outreach, education, assessments, tool creation and trust building, PSM India officially launched in December 2010. It held two public events in Mumbai and Delhi. As part of the launch, PSM-India announced the creation of a toll-free helpline (1800-11-4424), operated 24 hours a day, 7 days a week, that consumers can call if they have questions, think they have received a spurious drug or to report an incidence of spurious medicines being sold.

Importantly, Mr Misra and the PSM-India team have created a recognized, useful resource for policymakers and the public, and are building relationships and engaging these communities on these fronts. For example, Mr Misra and PSM India have established themselves as the 'go-to' resource on counterfeit and spurious drugs in India. Mr Misra continues his advocacy through disseminating PSM-India success at speaking around the globe, and is involved in a variety of initiatives across India to promote safe medicines to patients. He is in regular communication with the Drug Controller General in India, as well as US Government officials in India, to further both domestic and international cooperation.

FUTURE EFFORTS

Given the success in India and the continued call for greater global cooperation, in 2011 the partnership is beginning work in four other countries, China, Thailand, Brazil and South Africa, to lay the groundwork for possible PSM affiliates. Similar to previous efforts, PSM has once again established an ambitious travel schedule to meet with key stakeholders in each region and complete the due diligence necessary to create the beginnings of a successful organization and effort.

CONCLUSION

It is only through true PPPs that PSM and its affiliates internationally can be successful in the fight against counterfeit medicines. The counterfeiters have the luxury of acting quickly and alone, leveraging the reach of the Internet and a global marketplace to make the most money and harm the most people. Coordinated PPPs can beat them at integrity and rallying together with one another, globally, to shut them down.

Yet no partnership, PSM included, can do it in isolation. Indeed, the United States as a sovereign entity cannot do it alone, nor can even the World Health Organization. We must have sustained, global cooperation involving a broad range of public and private stakeholders to have any chance of achieving this goal. I am confident that through the successful PPP model we have established with PSM and PSM-India, public health and patient safety

issues can be effectively addressed in the global fight to curb counterfeit medicines.

REFERENCES

1. Akintotoya, A., Beck, M. and Hardcastle, C. (eds.) (2003) *Public Private Partnerships*. Oxford, UK: Blackwell Publishing.
2. Liang, B.A. (2006) Parallel trade in pharmaceuticals: Injecting the counterfeit element into the public's health. *North Carolina Journal of International Law and Commercial Regulation* 31(4): 847–889.
3. Partnership for Safe Medicine Members. (2011) http://www.safemedicines.org/psm_members.html.