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Report

# Assurance for safe medical products: protecting public health through unified global action

Tuesday 17 – Thursday 19 January 2017 | WP1528

**Held in Abuja, Nigeria**

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## Background

The provision of safe and effective medicines and health products represents a core component of a functional health system and is also fundamental to the mission of international health financing organizations, including multilateral and bilateral institutions. The transnational challenge posed by substandard; spurious; falsely-labelled; falsified; and counterfeit (SSFFC) medicines and health products and underperforming medical product supply chains places a disproportionate burden on less developed countries and threatens to undermine hard-won gains made by global public health organizations. SSFFC medicines are also a critical factor in the rise of deadly drug resistant infections globally. Underdeveloped supply chain assurance, weak health systems, lack of transparency, and inconsistent medical regulatory capacity erode sustainable efforts to protect public health and prevent diversion of medical products.

The Global Steering Committee (GSC) for Quality Assurance of Health Products represents a voluntary coalition of health financing and other international organizations that work in growing collaboration with national authorities and the private sector. The meeting galvanized senior policy support for joint GSC initiatives that are practical and outcome oriented, and sustainable solutions for combating the production and distribution of SSFFC medicines and health products.

Aid agencies spend hundreds of millions of dollars to deliver lifesaving medicines and medical products. It is our obligation to ensure that they are of the highest quality and that they reach their intended target. Aid agencies also have an obligation to work closely with national authorities as it is sovereign countries that are on the front lines and will ultimately be held accountable by their people and their leadership.

Donor governments rightly demand value for money, transparency, and successful health outcomes for the taxpayer resources they use. Scrutiny is high, particularly in London and Washington, underscoring the need for systems and investments in sustainable solutions, and commitment to invest in collaboration.

## Key points

We see enhanced collaboration among aid agencies looking at how to share information, exploit joint programming, and avoid duplication. As aid budgets come under increasing pressure to demonstrate impact and value for money, such collaboration is a necessity. Agencies want to make sure that their own supply chains are in good shape without leakages and closing off opportunity for falsified and substandard quality medicines to enter. The Global Steering Committee is an established voluntary network meeting regularly to promote these efforts.

Similarly, regional organizations are working together to improve regional regulatory harmonization and coordination. This work is well advanced in many areas and may be an excellent vehicle for shared focus on quality assurance measures and supply chain reform.

Efficient, transparent, and effective supply chains undergird the work of international agencies investing in health. Commercial supply chains must also deliver safe medicines and medical products. Public and commercial access to safe medicines and products must mutually reinforce each other.

USAID and the Global Fund in particular are currently undertaking significant investment and focus on supply chain reform. Donor governments need to take an interest in the capacity of national partner countries to effectively administer and govern their pharmaceutical markets. Technologies such as track and trace and barcode authentication offer simple solutions and promise significant improvement in supply chain security.

National medical regulatory authorities and other national agencies are the tip of the spear when it comes to protecting against falsified, substandard, and diverted medicines. Yet, they often lack the resources to fulfill their mandate. International partners need to focus more efforts on investments in capacity building and training for these bodies, and national task force models promote coordination in a way that brings much needed “whole of government” responses.

The general public is most impacted by the distribution of falsified and substandard medicines. Diverted medicines also leads to stock outs and shortages, inflated prices, and opportunities for insertion of fake versions. Regulators are challenged with dilemmas in deciding how much to communicate about threats, how best to engage civil society, and how to optimally configure reporting systems in their countries.

There is a fine line between protecting public health through public information and creating fear or panic. Regulators must find the right balance that informs patients and helps protect safety but does not undermine faith in health programs and the health system.

Aid agencies and national authorities may look for opportunities to work more closely with manufacturers to more effectively ensure safe delivery of their products through legitimate distribution channels.

Often fake medicines found in one country show up in another. Better information exchanges are needed at the national, regional, and international levels to stop the flow of dangerous products. Liaison and joint task force engagement models offer promise for improved coordination and collaboration across agencies and borders. Cooperative efforts must ensure that quality assurance, transparency, and protection against fake and diverted medicines find a place in ongoing regional regulatory harmonization frameworks.

African regional bodies, starting with the East African Community (EAC) and moving to the Economic Community of West African States (ECOWAS) and the Southern African Development Community (SADC), are making good progress on regional regulatory harmonization of policies and procedures. Quality assurance and supply chain integrity must be better integrated under this broader reform umbrella.

The Global Health Assurance Partnership (GHAP) has been highlighted as a useful non-profit association able to support needed market surveillance and engage with national authorities to provide training and equipment.

GHAP's National Engagement Strategy prioritizes working with, by, and through, national agencies on the ground, including regulatory and law enforcement, and providing them with special equipment for new forensics units.

## SSFFC medicines and health products in Africa: How do we understand the threat?

1. SSFFC medicines threaten lives, reputations, and trust, and the loss of confidence in health services can be very corrosive of governance. The obligation of regulatory agencies and international organizations is to ensure that the highest quality medicines are reaching those who need them most.
2. While there are many facets to the challenge of SSFFC medicines, the perennial problem of corruption is central to the issue. This is not unique to Nigeria or Africa, but they are at the heart of the safe medicines issue. International and local partners need to find ways to better work together more effectively hold authorities to account and address corruption. In a time when DFID is also experiencing increased scrutiny of its programs, the ability to show value for money is increasingly important for demonstrating relevance and importance of aid programs.
3. Efforts to address the threats of SSFFC medicines must first recognize the importance of defining the issue and the experience of frontline agencies confronting it on a daily basis.
4. In the Ugandan experience the biggest problem is substandard and poor quality medicines making false claims about their efficacy.
5. A number of chronic challenges also limit success for many countries, including:
    - Fear of retribution: there is sometimes a fear of reporting counterfeit distributors among public and stakeholders due to fear of reprisal from manufacturer or distributer. It's also tricky for regulators to declare substandard products, which can further undercut their legitimacy.
    - Follow up: it is also difficult to take concrete action about substandard products after notifying the supplier of issues, and following up to ensure removal from the market is difficult.
    - Investigatory hurdles: there is often insufficient investment in investigations as well, which compounds the inability of governments to take concrete action, and re-evaluate programs and procedures.
    - Effective communication: when products are confirmed to be substandard, there remains a high risk of effectively communicating actual risk.
6. The Ethiopian case provides many insights into major ongoing challenges in the fight against fake medicines. Pharmaceuticals are key to strong healthcare systems, and there are particular challenges with substandard medicines for countries with large populations and porous borders. 90% of some countries' medicines are imported from abroad. They also experience many substandard and unregulated products, and securing ports of entry and supply chains is very difficult.
7. A strong strategy for eradicating SSFFC medicines requires 3 lines of effort focusing on prevention, detection, and response.
8. Prevention requires interception before the entry of SSFFCs into supply chains and involves a solid legal framework, effective administrative measures and strong criminal law, as well as the registry of products, and efforts to increase the supply of medicines to expand access to legitimate products. It also requires the systematic inspection of facilities, especially wholesalers, importers, and retail markets. Importers with high value products must be particularly scrutinized, and intelligence and market surveillance investigators can "red team" supply chain and market systems to identify weaknesses and vulnerabilities.

9. Capacity building efforts should focus on coordinating across agencies, especially customs and the judiciary, and strengthening health regulatory systems.

10. The Zambian experience is particularly complex, with a population of 15 million, many borders and eight neighbors, it underscores the complexity of border management. HIV aids (12%) and malaria are two of biggest public health threats. With a supply chain worth $140M USD, there is a high risk and attraction for falsification. ZAMRA, the national regulator, has recently updated its regulatory framework, and Zambia is also the beneficiary of a new national quality control laboratory, which increases capacity for regulation, in what is probably the continent's second largest supply chain system, with enormous complexity and risk.

11. The lack of capacity in many public labs may mean that options should be explored allowing regional or private labs to be used in product testing and market surveillance. However, training police and customs officials in visual and physical inspection techniques can still be very effective in improving the ability of governments interdict smuggling of fake medicines

12. Pharmaco-vigilance systems are thus only effective where healthcare professionals are encouraged to report, and not all those who report fake products are themselves honest.

13. Niger also faces a complex environment for safe medicine assurance, with long borders with neighbors and supply chain issues. The legal system is arguably the weakest link in Niger, and improved collaboration between authorities is crucial, especially at border points. Efforts to create links with customs for entry are ongoing and need support, but lack of capacity amongst inspectors remains an issue, as well as poor coordination with neighbors. Training inspectors for detection and to understand the broader health threats posed by fake medicines continues to be an issue as well, especially in rural areas.

14. In some countries the weakness of the legal authority is compounded by the dilution of regulatory authority between several poorly coordinating agencies, with weak collaborative capacity and serious funding shortfalls. Donor efforts could achieve more sustainable results by supporting the capacity of these coordinating bodies.

## Model engagement between health financing institutions and national authorities: how do we build joint capacity to protect against SSFFC products?

15. There is growing recognition of the importance of regulatory agencies 'owning' efforts and taking leadership. While its initial focus was on registration and good manufacturing practices (GMP) inspections and quality management systems allowing for easy data exchange between agencies, World Health Organisation (WHO) also provides technical support with a reviewed overall strategy for the African Medicines Regulatory Harmonisation (AMRH). There is now an increasingly recognized need to broaden the scope for the AMRH initiative to focus more on pharmacological vigilance and surveillance.

16. The Global Steering Committee (GSC) will now merge with AMRH activities under the broader umbrella of regional regulatory strengthening. National authorities specifically asked for the integration of quality assurance coordination and support, which is supported by the GSC coalition.

17. The fight against false medicines should not be confused with debates about generics and name brand drugs. Many fake products had no active pharmaceuticals ingredient (API), and research findings have actively demonstrated that issues of falsified medicines were not simply affecting branded medicines, but generics as well. Organized crime networks know that generics are getting increasing market share, and are increasing falsifying them as well. It is now clear that this is a public health rather than intellectual property issue, as generics are just as threatened by criminal markets.

18. In an era of increasing scrutiny from donors to ensure value for money in efforts, it is key

to recognize the explicit nexus between issues of diverted and fake medicines, and important to acknowledge that diversion of legitimate medicines is not a benign issue. Shortages in legitimate markets push neediest into black markets and compounds mistrust in legitimate markets.

19. These efforts have highlighted the importance of affordable and reliable rapid authentication devices, enabling mobile teams to make immediate decisions. This successful piloted Zambian model provides a blueprint for effective collaboration and will be expanded to other countries in 2017, with Global Fund grants providing financial assistance.

20. Support to increase capacity to, train and equip, and, track and trace, is particularly necessary. Often weak legislation also hampers the efforts of regulators, and sometimes even massive shipments of diverted and falsified drugs are met with only small and non-deterrent fines.

21. Dealing with upstream and downstream aspects of fake medicines needs to be simultaneous. For example, there has been a change over the last few years in the approach of Chinese authorities, including an awareness of negative public and media attention, as well as more serious responses from Chinese officials due to the negative effects of safe medicines on the Chinese population.

22. In Ghana, efforts often work through the Economic and Organized Crime Agency. Judges sometimes want to know causation however, and request proof that drugs have caused damage to patients. Many other judiciaries are similarly unaware of risks and broader problems. Even when legal sentences are strict, judges are reluctant to enforce them in the absence of broader understanding of the severity of issue.

## Strengthening supply chain assurance: how to prevent the spread of SSFFC and diverted medicines and health products

23. Efforts around supply chain assurance are an area of broad agreement and interest, including from aid and donor agencies, and it is critical to improve systems in partner countries.

24. USAID Nigeria supports health programs and commodities, as well as working to strengthen NAFDAC labs and the capacity of governments for local procurement.

25. There is also growing awareness around the importance of strengthening capacity in inventory, software, and warehouse management, and the utility of sometimes using private sector options to manage warehouses. The issue of data management is a major challenge, as public health workers seek to more effectively share data to inform supply chain decisions. The importance of data for evidence-based policymaking and improving the quality of health systems governance should not be understated.

26. The Global Fund, for example, was previously a health financing institution but has become increasingly involved in supply chain and full assurance. There is a need for recipient countries to be more demanding in insisting on tools for higher compliance.

27. National authorities would benefit from a centralized documentation system or resource that catalogued best practices being undertaken and piloted in different countries. On track and trace, member states set up working group that is soon to publish a paper listing all countries with current program, including benefits and downsides, and assessments of their experience.

28. GS1 is the global standard for barcode identification, and seems to be the one around which most institutions are converging. One potential role for donor agencies could be to provide short cheat sheets to help countries become more compliant. Additionally, heads of medicines regulatory authorities have similarly identified this as being important, and raised concerns about the lack of harmony amongst other companies. Pharmaceutical trade is global, so systems must also be global to make sense of this. Barcodes do cost more, but would likely be pennies on the dollar compared to efficiency and savings made

from improved assurance.

29. In law enforcement and regulation, and the objectives of ‘prevent, protect, and respond’ should all be seen as complementary. However, there will always be enterprising criminals, and where increased instances of diversion are occurring, international partners need to ensure that their responses continue to support national authorities. The Global Fund has a capacity building fund as an integral part of its work for this reason, as it recognizes the need to grow supply chains to reduce reliance on short term consultants. It’s also important to recognize importance of the supply chain skill set. Boots pharmacy warehouses in the United Kingdom are operated mostly by logisticians and supply chain experts, with formal training in the requisite skills.

30. One basic aspect of track and trace is a ‘parent-child’ relationship along the whole supply chain, allowing for a more clear chain of custody along the production and dissemination process. While such efforts are key, there will always be a clear need for a multi-layered approach involving continual surveillance and the ability to physically inspect a product.

## Capacity building for medical regulatory and national enforcement authorities

31. Long term multi-year training programs are necessary for constructive support, and these should also be augmented with the inclusion of other specialist agencies. It’s also necessary for partners to insist on the importance of inter-agency training rather than replicating silos. Iterative workshops should include tailored training from specialist agencies supporting investigations, operations, and major case management capacity, ensuring that investigations are sustained beyond the initial raids, and are able to prosecute more than just low-level offenders. Effective investigations must be able to bring down leadership figures, wholesalers, suppliers, shippers, and government suppliers. National engagement strategies must also be attentive to the nuances of handling sensitive information, cultivating whistle-blowers and informers, and human intelligence.

32. The lack of human resources capacity affects even the United States Food and Drug Administration (USFDA). Growing out of generic drug scandals in the early 1990s where reviewers were found to be taking bribes, the agency was given arrest, search, and seizure powers to ensure that it was equipped with all relevant and appropriate authorities.

33. These human resource shortages highlight the role of task forces in leveraging local staff. The USFDA has been able to put liaisons in Interpol, Europol, and similar organizations, acting as force multipliers for their reach and awareness. This provides direct daily contact with 40 countries’ law enforcement agencies. Casework deals with human drugs, devices, food, and biologics. Previously when targets were overseas, the USFDA was forced to immediately close cases, but is now able to pursue convictions given its greater cooperative reach. Some of the most significant case work has arisen from Europol collaborations.

34. Only four out of fifteen ECOWAS member states have well developed regulatory agencies, though other countries have much weaker systems. These countries need support in developing these systems in the form of capacity building and tools.

35. Effective regulation cannot be taken for granted; internally generated revenue can be hard to come by, and running operations takes resources. Given that national authorities need to monitor products they receive from donors, a fraction or percentage of donor gifts could be given to support and develop the regulatory capacity of recipient nations.

## Raising public awareness: whose responsibility

36. A number of WHO member state technical groups carry out ongoing work, including an examination of the socio-economic impacts of false and substandard medicines. Figures

for these are difficult, but health economists are examining published literature, and will estimate prevalence and cost of damage of substandard and falsified medicines. This will set the baseline on the best available material.

## Communication interventions: social and behavior change communication

37. Other initiatives such as HC3's 'Roll Back Malaria' program seek to improve health outcomes by strengthening capacity for social and behavior change communication programs (SBCCs). This program sought to target public awareness and behavior around SSFFCs but realized the problem was more complicated than usual public communications strategies, in part because fakes were too convincing to expect consumers to educate and discriminate themselves. This led to a broader effort not just to educate, but to also change attitudes and promote healthier behaviors, recognizing the need to both improve knowledge of danger, and practical steps for reducing it.

38. Products involved fact books, news spots, advertisements, as well as media training. Post-campaign analysis demonstrated high exposure rates, greater awareness, and improved behavior around buying and selling, and increased intention to change behavior. Receiving multiple sources of information helped encourage better decisions.

39. Campaigns must begin with improved situational awareness around dangers, social consequences, and willingness to report pilferage in some communities. Successful campaigns have included tools for journalists, and starter kits are available and have underscored the importance of communication systems that enable professionals to be able to create an alert. These programs provide important lessons for crafting effective and comprehensive strategies in the future.

40. Faith communities and social actors also have an important role to play, and have been effective even before villages were road accessible and otherwise connected with the rest of their country. There is an opportunity to take advantage of these mechanisms to help communicate and raise awareness around these issues. Some efforts in Nigeria have trained 660 Pastors and Imams to communicate messages. Donor agencies and international organizations can work better through these networks, but there is a need to properly equip Pastors and Imams so messages can go out. The more channels through which people are exposed to a message, the more likely they are to change behaviors, therefore engaging religious leaders is key.

41. Responsible media engagement and socialization are very important aspects of planning, as are the training and sensitizing of media before crises. Some changes are easy in short term, and others require long term engagement, but the key is to have plans in place.

## Enforcement against SSFFC medical products: how can front line agencies act locally but think globally?

42. Generally speaking, the role of enforcement around falsified medicines does not lie within a single agency like a regulatory authority, because most activities go beyond medicine to criminal activities. Regulatory agencies have their own import and manufacturing registrations, so mechanisms are in place but SSFFC issues run wider. Issue of borders for countries with many neighbors is particularly complex.

43. Given that only legitimate actors will respect import rules, regulators are more likely to find SSFFCs already in the country. Smugglers will use permissive borders with less capable neighbors to gain entry for their products. This underlines a need for a better mechanism to actively think of networks regionally, including mutual and common ports of entry, as well as underscoring the need for harmonization and common standards amongst regulators so they can seize fake products passing through their countries. Criminal syndicates are also very well-funded and ruthless, so regulators need to ensure that inspectors are safe and secure. In many cases, bad actors can be violent and

protected by politicians and those in power.

44. Mechanisms such as inspections, anonymous tips, technology, and labs to confirm counterfeits are important tools for regulators, whose cooperation with other law enforcement agencies needs to involve intelligence gathering, including use of informants and other surveillance techniques. Inspectors must preserve secrecy around planned raids to ensure operational security and avoid tipping off criminal actors.
45. Teamwork amongst agencies also has the potential to reduce corruption, as DTIU and other agencies collaborate, they become like bricks that work together, and can even reduce political interference and patronage from interfering with investigations. This coordination can also open up access to better training and financing, rather than forcing each agency to come up with its own funding and connections.
46. Regulation is dynamic, and the sophistication of fake products is constantly improving, so there is a need for regular training. Additionally, states are only as successful as the weakest neighbors in their region, so the need for regular collaboration is key. If less capable states are left behind then real progress will never be made.
47. The importance of pooling resources is hard to over emphasize, and is necessary as much as is feasible and practical. In the same way that best practices for food and cosmetic products have been harmonized, there is a need for this on the issue of safe medicines.
48. A platform and repository for relevant resources and case studies would be very useful. While there is not a need for entirely new structures, there is a need for better coherence, coordination, and resourcing. The Gates Foundation Africa Rural Connect (ARC) initiative is an example of how this might work.
49. Further conversations could examine in more depth how supply chains could be redesigned to increase efficiency, and how donor agencies could be better encouraged to invest in logistics capacity, and ensure that recipient countries have not just the products but also the tools, techniques, and capacity to effectively control and administer them.
50. It's important to look for opportunities in which aid agencies can interact directly with frontline agencies on the ground and 'meet in the middle'. The private sector needs to be engaged and harnessed and a part of this discussion going ahead, as they have the tools, resources, and expertise. The GSC is a platform to coordinate many aspects of these questions, having the right diversity of membership and ability for information sharing. The proliferation of new platforms and working groups should be treated with caution however, and primary focus should remain on making current structures work.
51. Aid agencies have a catalytic role in funding, but their efforts alone will be insufficient. Agencies that are providing hundreds of millions of dollars of product to developing countries need to invest better in national authorities to ensure they have the resources needed to administer their markets and supply drugs effectively. This requires a long term sustainable approach to embedding these solutions into the funding structures of aid agencies.

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