An Executive Briefing on Decision Making Using Estimates of
Loss Due to Counterfeit Medicine Activity

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A shortened version of the title might be “Thanks for telling me how much we a losing from counterfeit medicines. How do we best use this information?” another question might be “How reliable are these estimates?” This research brief provides some guidance, and some suggestions, to these questions.

In the continuing fight against counterfeit competitors, it’s not enough to only look at the numbers. It’s accepted they will mostly likely be large. The real question is, can are we doing anything about it? And what is he ROI?

Loss Estimates

There are widely varying estimates of loss due to counterfeit medicine activity. And that variability underscores the skepticism about the accuracy of the estimates. This shouldn’t be surprising. The illicit nature of counterfeit trade it difficult, if not impossible, to work with reliable data. Many loss estimates are made using “informed guesses”, direct testing of a samples of medicines, surveys, indirect measures of activity, and extrapolations from seizure data.

Collection and methodological issues notwithstanding, consider why having estimates is important.

Strengths

1. Estimates of loss raises awareness. Even imperfect estimates help frame the problem as viewed from alternative perspectives – industry actors, policy makers and the public.
2. Loss estimates can be viewed as the required support needed for investment in anti-counterfeiting measures, enforcement and policy changes.
3. Consistent approaches to estimation, even if the results are “not perfectly accurate”, nonetheless provide a means for analyzing trends.
4. Loss estimates help guide resource allocation for anti-counterfeiting efforts by high-lighting high-risk regions, products and channels.

There are limitations as well. Among them are:

Weaknesses

1. Issues such as incomplete data, gaps in data collection, and coverage limitations. This is not surprising since direct data on counterfeit activity is unobservable.
2. There are no standard accepted mythologies for estimating counterfeit losses.
3. Losses focus on financials such as direct revenue loss. Indirect costs such as patient harm, brand erosion and public health impacts are often underestimated or ignored.
4. The impact of counterfeiting is not uniform across regions and products. Hence aggregate estimates of loss are less useful for decision making.

Executive Skepticism

There is a high level of skepticism for data analytic methods.

1. **There is an inherent distrust of "soft" data**.
   Counterfeit loss estimates often involve assumptions, projections of loss sales that are hard to understand since they didn't happen and estimates of intangibles like patient safety. Rather executives are accustomed to hard data such as sales, costs, and profits.
2. **Executives typically focus on tangible ROI**.
   They need to see how investing in understanding counterfeit losses and countermeasures will directly benefit the bottom line. Models often seem as too abstract and disconnected from real-world financial performance.
3. **"We Haven't Seen it/Felt It" Mentality**.
   If counterfeiting hasn't been perceived as a major, immediate crisis, executives might be complacent or dismissive. They may think existing security measures are sufficient or that the problem is overstated.
4. **Preference for Action over Analysis.**
   Executives are action oriented. Spending time and resources on modeling and estimating losses might seem like analysis paralysis, delaying concrete actions.
5. **Distrust of "Black Box" Models**
   If the methodology behind the loss estimates isn't transparent and easily understandable, executives might be wary of relying on something that feels like a "black box" spitting out numbers without clear justification.
6. **Budgetary Constraints and Prioritization:**
   Every investment must be justified against competing priorities. Executives need to be convinced that addressing counterfeiting (based on these estimates) is a higher priority than other potential investments.

The problem with estimates of loss

The range of estimated losses due to counterfeit medicine varies from 5-10 billion (OECD estimates) to over hundreds of billions of dollars (WHO). From an executive's perspective, there is no consistency nor is there a generally accepted methodology behind estimates of

loss. Hence, there is a large degree of skepticism in valuing current research on loss. More importantly, how do these estimates relate to company's portfolio and sales?

To overcome this skepticism, an approach must be created that covers both strategic and tactical decisions that are tailored to executive thinking. Or simply, what will get executive buy in?

Strategies to gain executive buy-in:

1. **Ground the Model in Hard, Verifiable Data:**

   Begin with data executives already trust and understand:

   Confirmed Seizures & Recalls: Quantify the *actual* volume and value of counterfeit products seized or recalled. This is tangible evidence.

   Customer Complaints & Adverse Events: Track complaints related to product quality, ineffectiveness, or adverse reactions that could be linked to counterfeits.

   Sales Data Anomalies: Analyze sales trends in specific regions or product lines for unexplained dips that might correlate with suspected counterfeit activity.

   Market Research (with Caution): Use reputable market research firms but be transparent about the limitations and assumptions inherent in survey data on counterfeiting.

2. **Focus on Direct Financial Impact First**

   Prioritize estimating direct revenue loss from counterfeit sales displacing legitimate sales. This resonates most directly with executives. Then layer in the indirect costs.

3. **Transparency of Methodology:**

   Clearly explain the model's methodology, assumptions, and data sources in non-technical terms. Executives need to understand the logic behind the estimates, not necessarily the complex algorithms. Visual aids (flowcharts, diagrams) should help.

4. A**cknowledge uncertainty.**

   Present estimates as ranges (e.g., "losses are likely between $X and $Y") and, if possible, conduct sensitivity analysis to show how the estimates change under different assumptions. This demonstrates rigor and intellectual honesty, rather than presenting a single, potentially brittle number.

5. **Quantify the "Soft" Costs in Financial Terms (As Much as Possible):**

   Brand Damage Valuation: Explore methodologies to estimate the financial impact of brand damage. This is complex, but consider:

   Customer Lifetime Value (CLTV) Impact: How might counterfeit incidents erode customer loyalty and reduce CLTV?

   Market Value Impact (Stock Price Analysis): Are there examples of publicly traded pharma companies where counterfeit crises impacted stock price? (Use with caution, correlation is not causation).

   Cost of Brand Repair: Estimate the costs of public relations campaigns, brand rebuilding efforts, and marketing initiatives needed to recover from a significant counterfeit incident.

6. **Patient Harm & Liability Risk:**

   Potential Legal Costs: Assess the potential liability and legal defense costs associated with patient harm caused by counterfeit drugs.

   Regulatory Fines and Penalties: Estimate potential fines from regulatory bodies for failing to control counterfeiting.

   Public Health Costs (Indirect Impact): While harder to directly link to the company's bottom line, highlighting the broader public health impact can resonate ethically and underscore the scale of the problem.

7. **Connect Loss Estimates to Tangible Business Decisions and ROI:**

   Show how estimates inform actionable strategies: Explicitly link the loss estimates to concrete strategic and tactical decisions (as outlined in the previous answer). Demonstrate that these estimates are not just academic exercises but tools for better decision-making.

   Develop ROI Scenarios for Anti-Counterfeiting Investments: Create clear ROI scenarios for different levels of investment in anti-counterfeiting measures. Show how these investments can *reduce* the estimated losses, resulting in a net positive financial outcome. For example:

   "Investing $X in advanced packaging is estimated to reduce counterfeit losses by $Y over 5 years, resulting in a net ROI of Z%."

"Increased supply chain monitoring costing $A is projected to prevent B counterfeit incidents annually, saving the company $C in lost sales and brand damage."

8. **Benchmark Against Industry Peers:**

   If possible, present data or case studies showing how other pharmaceutical companies are quantifying counterfeit losses and using these estimates to justify anti-counterfeiting investments. Peer benchmarking can reduce skepticism and demonstrate industry best practices.

9. **Present the Information in an Executive-Friendly Format:**

   Concise and Visual Reports: Avoid lengthy, technical reports. Use executive summaries, dashboards, and visually compelling charts and graphs to present key findings.

   Focus on "So What?" and "Now What?": Executives want to know the implications ("So what?") and the recommended actions ("Now what?"). Structure presentations around these questions.

10. **Present to Key Decision-Makers Directly:**

    Engage with executives in direct presentations and discussions. Be prepared to answer tough questions, address skepticism head-on, and demonstrate confidence in the methodology and findings.

11. **Use Trusted Messengers:**

    If possible, have trusted internal advisors (e.g., senior finance executives, respected operations leaders) or external consultants with industry credibility present the findings.

12. **Start Small and Build Credibility Over Time:**

    Pilot Projects: Consider starting with loss estimation in a specific region or for a specific product line as a pilot project. Demonstrate the value and accuracy of the estimates in a controlled setting before scaling up.

    Iterative Refinement: Treat the loss estimation model as a living tool that can be refined and improved over time as more data becomes available and as the company's understanding of counterfeiting evolves. Show a commitment to continuous improvement and data-driven decision-making.

13. **Track and Validate Results:**

    After implementing anti-counterfeiting measures informed by the loss estimates, track the actual impact on counterfeit incidents, seizures, customer complaints, and sales trends. Use this real-world data to validate the model and further build executive confidence.

Using Loss Estimates

How could estimates of counterfeit loss be used? There are both strategic and tactical decisions that could benefit from counterfeit loss estimates.

Strategic Decisions

Under strategic initiatives are investment in anti-counterfeiting measures covering technology, packaging, and supply chain security. The objective is to connect this investment to ROI.

Pricing strategies focus on how counterfeit losses influence the pricing of legitimate drugs. Are the impacts also indirect? For example, is the cost of protection factored in?

There is realm of geographical focus. Are some markets more prone to counterfeiting? How does a geographical analysis factor into marketing and investment decisions. Is the ROI from technology higher in advanced markets?

Tactical decisions

How are packaging and labeling decisions evaluated? Is there a direct ROI (reduced loss)?

How successful is day-to-day supply chain monitoring?

How are communications (and public relations efforts) is damage control if counterfeits are detected?

What is the status and success of legal action (and enforcement) to specific incidents?

For any decision, strategic or tactical, a central focus should be on ROI. Explicit conversations are required on how loss estimates are used to compute ROI for any anti-counterfeiting investment. Similar attention should focus on brand and reputation. How do counterfeit drugs damage brand trust and reputation? Loss estimates may help quantify the potential damage.

Summary

The following summarizes the types of strategic and tactical decisions that likely confront executives:

Strategic

1. Strategic - Anti-counterfeiting investment: *Why are loss estimates crucial?* To justify budgets for potentially expensive technologies and systems. Need to show the cost-benefit, and loss estimates provide the "benefit" side of the equation.
2. Strategic - Pricing: Less direct but could influence long-term profitability projections.
3. Strategic - Geographic Focus: *Why loss estimates here?* To prioritize resources and market strategies in higher-risk areas.
4. Strategic - Advocacy: *Why loss estimates here?* To provide compelling data to regulators and policymakers, making the case for stronger action.

Tactical

1. Tactical - Packaging: *Why loss estimates?* Might inform the *urgency* and *type* of packaging changes. Higher loss estimates might trigger faster, more comprehensive changes.
2. Tactical - Supply Chain: *Why loss estimates?* To justify investments in more robust monitoring systems and staff training. Also to prioritize where to focus monitoring efforts based on where losses are occurring or predicted to be high.
3. Tactical - Communication: *Why loss estimates?* To gauge the scale of potential reputational damage and inform the level and type of communication response.
4. Tactical - Legal: *Why loss estimates?* To determine the scale and priority of legal actions. Higher losses justify more aggressive legal pursuit.

Additional perspectives

Product Portfolio Strategy:

Portfolio Decisions

Given loss estimates, executives might re-evaluate their product portfolio, potentially prioritizing resources towards products less vulnerable to counterfeiting or more amenable to robust anti-counterfeiting measures. They might also decide to phase out or reformulate certain high-risk product

Influence of Loss Estimates:

If specific product lines are consistently targeted by counterfeiters (widely used and high valued medications), strategic decisions could involve:

Formulation Changes: Making products harder to copy or less attractive to counterfeiters.

Concentration on Products with Stronger Protection Options: Prioritizing products where advanced anti-counterfeiting measures are more feasible and cost-effective.

Portfolio Diversification: Shifting focus towards therapeutic areas or product types less prone to counterfeiting risks.

Brand & Reputation Link:

Strategic portfolio decisions can be communicated to reinforce brand values. For instance, publicly announcing the discontinuation of a highly counterfeited product line to protect patient safety demonstrates a strong commitment to ethical principles and brand integrity.

Tactical Decisions (Short-Term Actions & Operations)

Estimates of losses also drive immediate tactical decisions, focusing on day-to-day operations and responses to specific incidents:

Resource Allocation for Investigations and Enforcement:

Decision: Executives will decide how to allocate budgets and personnel for investigating counterfeit incidents, gathering evidence, and pursuing legal action against counterfeiters.

Influence of Loss Estimates: High loss estimates will justify increased spending on investigations and legal teams. Tactical decisions will be made on prioritizing cases based on the scale of the counterfeit operation, potential patient risk, and estimated financial and reputational damage. ROI calculations for legal actions will be heavily influenced by these loss estimates.

Brand & Reputation Link: Visible and successful enforcement actions can send a strong message to counterfeiters and reassure stakeholders about the company's commitment to protecting its products and brand. Publicizing successful raids or convictions, when appropriate, can act as a deterrent and enhance reputation.

Supply Chain Monitoring and Intervention:

Decision: Tactical adjustments to supply chain monitoring, audits, and interventions will be made based on where counterfeiting vulnerabilities are identified or suspected.

Influence of Loss Estimates: Loss estimates can pinpoint weak points in the supply chain (e.g., specific geographic regions, distribution channels, or product types). This allows for targeted tactical interventions such as:

Increased Audits and Inspections: Focusing on higher-risk points in the supply chain.

Enhanced Tracking and Tracing: Implementing more rigorous monitoring of product movement.

Rapid Response Teams: Deploying teams to investigate and address suspected counterfeit incidents swiftly.

Communication and Crisis Management:

Decision: Tactical communication strategies and crisis management plans will be activated when counterfeit incidents are detected, especially if patient harm is suspected or confirmed.

Influence of Loss Estimates: The scale of estimated losses, particularly those relating to patient harm and brand damage, will dictate the intensity and type of communication response. Tactical decisions will involve:

Public Announcements and Recalls: If patient safety is at risk.

Targeted Communication to Healthcare Professionals and Patients: Providing accurate information and guidance.

Crisis Communication Plans: Activating pre-prepared plans to manage media inquiries, stakeholder concerns, and potential reputational damage.

Return on Investment (ROI)

ROI is a central theme linking loss estimates to decision-making. Executives will constantly evaluate:

ROI of Anti-Counterfeiting Investments:

Is the cost of implementing new technologies or measures justified by the *avoided losses* (both direct and indirect) as estimated?

ROI of Legal and Enforcement Actions:

Will the cost of investigations and lawsuits be offset by recovered damages, deterrent effects, and brand protection benefits?

ROI of Communication and Crisis Management:

Will investing in proactive communication and robust crisis management plans save the brand from more severe long-term reputational and financial damage?

Finally

Accurate and comprehensive loss estimates are the numerator in these ROI calculations. Without them, it's very difficult to justify significant investments in anti-counterfeiting activities.