EMHN
Emerging Markets Health Network

FEB
2013

EMHN BRIEFING No.1

# Fake medicines in Asia

*Philip Stevens & Dr. Helmy Haja Mydin*


## Summary

**Fake medicines - which are either criminally motivated or the result of lax manufacturing standards - are a worsening problem, particularly in Asia. In some of poorer parts of the continent, up to a quarter of medicines fail quality tests.**

**Evidence shows that cheap generic drugs are the most faked medicines in Asia, although there appears to be a particular problem with anti-malarial drugs in places such as Laos and Cambodia. China and India appear to be production hotspots.**

**Producers and purveyors of fake medicines are exploiting the increasing globalisation of the pharmaceutical supply chain, poorly defined and enforced civil and criminal laws, and a lack of an international definition of what legally constitutes a fake medicine.**

**International efforts to combat fake medicines have been hampered by the inability of countries to agree on a legal definition for fake medicines. Legal scholars and health experts are now pushing for a global treaty to correct this problem and allow for greater cooperation between national authorities, but this will be many years off.**

**At any rate, a treaty will only be as effective as the legal and regulatory enforcement capacity in the worst affected countries. In many countries, general weakness of the rule of law is at the heart of the problem of fake medicines, so it is unclear how adding more and stricter laws and regulations will address this very basic shortcoming.**

**Technology can help legitimate manufacturers protect their brands, and this is discussed in the next EMHN briefing paper.**


Producers of fake medicines are evolving from basement operations to manufacturing on an industrial scale.

While consumers may not care if the handbag or pair of trainers they buy is fake, a medicine that is not what it claims to be is no laughing matter. At best, a fake medicine will do nothing to relieve a patient's condition: at worst, a fake medicine containing toxins such as arsenic or anti-freeze can kill.

Yet fake medicines are a booming global trade. Producers of fake medicines are evolving from basement operations to manufacturing on an industrial scale. A diverse range of players are involved in their manufacture and distribution, including medical professionals such as pharmacists and physicians, criminal groups, rogue local pharmaceutical companies, organised crime syndicates, corrupt government officials and terrorist organisations[1]. An increasing

body of evidence suggests that much of the supply of fake medicines originates in Asian countries including China and India.

Despite the seriousness of this global issue, the international community has yet to agree on the best path of action. An international treaty is being discussed, and most stakeholders call for greater regulation and harsher criminal sanctions. But are such measures necessarily the best way of tackling this complex problem?

This is the first of a two-part briefing which examines the scope and causes of the fake medicines industry, and assesses some of the international initiatives that are being implemented to tackle the problem. The second part will look at some potential solutions.

## What are fake medicines?

Broadly, fake medicines fall into two main categories: drugs with intentionally falsified ingredients, and those whose content is unintentionally substandard due to poor manufacturing practices.

- **Medicines with intentionally falsified ingredients** are usually made with criminal motives and often masquerade behind the brand or trademarks of legitimate manufacturers. The consumer has no guarantee as to the content of such products, which may contain therapeutically insufficient levels of active ingredient, inactive substances such as chalk, or even toxins. Such products are a major public health threat.

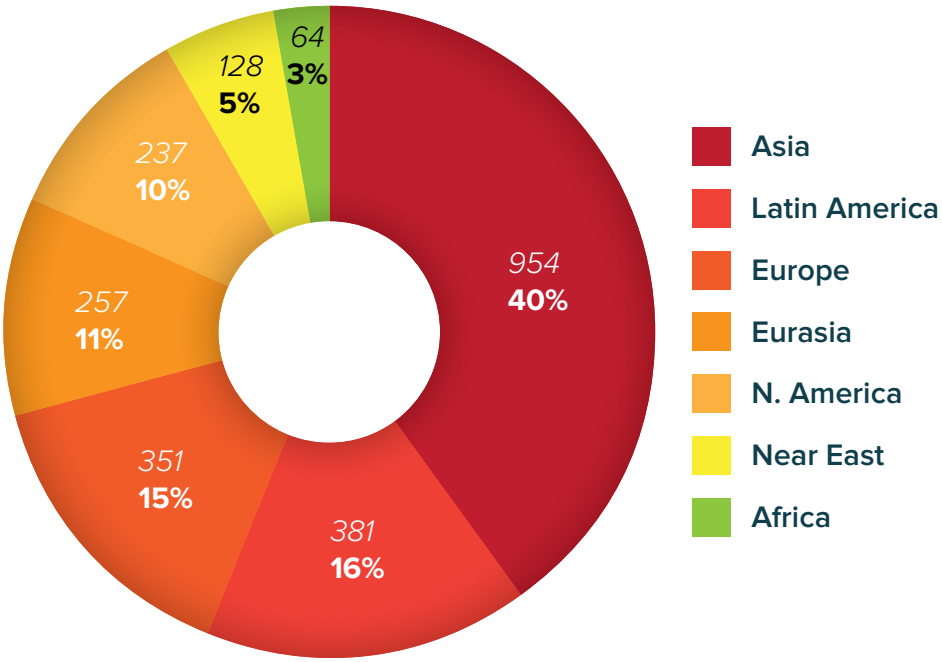
- **Substandard medicines**, which are legitimately manufactured but are sold to the consumer after undergoing one or more regulatory failures such as manufacturing error, degradation in transit or storage, or expiration. These medicines are likely to be therapeutically substandard, and therefore must be considered a public health threat.

*The most widely faked medicines in Asia are cheap off-patent drugs.*

In practice, overlaps between deliberately falsified and negligently substandard medicines are inevitable. Studies in locations suffering from poor quality drugs typically discover both. It can be extremely difficult to differentiate between the two, as it is not always clear whether the actions leading to faulty drugs were deliberate. Furthermore, the difference is of little concern to a patient harmed by bad medicine.

As it is difficult to distinguish between falsified and substandard medicines, and because they both pose a considerable threat to health, for simplicity this briefing paper refers to all such medicines as “fakes”.

*Figure 1:*
**Pharmaceutical crime incidents by region, 2011**




*Source: Pharmaceutical Security Institute 2011*

## How big is the problem globally?

The problem of fake medicines is clearly worsening, although the difficulty of identifying fake products makes it impossible to gauge its true extent. Until recently, the World Health Organisation (WHO) suggested that 10-30% of medicines circulating in lower and middle-in-

come countries were fakes; however it no longer cites a particular figure.

Some figures cited by international organisations give some indication of the extent of the problem:

- Between 10 and 30% of medicines in developing countries are fake, according to the International Medical Products Counterfeiting Taskforce [2]
- In 2011, 1,986 pharmaceutical crime incidents were documented globally (including counterfeiting, theft, and illegal diversion), with nearly half of seizures made by enforcement officials being of 'commercial size'[3].
- According to WHO, 50% of medicines purchased over the Internet (from illegal sites that conceal their physical mailing address) were found to be counterfeit[4].

## How big is the problem in Asia?

According to the Pharmaceutical Security Institute, Asia suffered from the highest numbers of incidents of pharmaceutical crimes in 2011 (although this may understate the extent of the problem in Africa, which generally sufferers from poor enforcement capacity) (Figure 1).

Fake anti-malarial drugs appear to be a particular problem in mainland South East Asia. A recent study found 38% to 53% of samples purchased from pharmacies and shops to be fake, with many packages bearing falsified security holograms[5].

Malaysia, a wealthier country with a relatively well developed regulatory and legal environment, has a fake medicine prevalence of roughly 3-5% of all medicines in circulation. By contrast, poorer countries tend to suffer from higher rates (Figure 2). For instance, the International Pharmaceutical Manufacturers Group (IPMG) in Indonesia has estimated that fake drugs constitute 25% of Indonesia's US$2 billion pharmaceutical market[6].

## Why is there an increase in fake drugs?

Fake drugs in recent decades have surged largely because the rewards of

*Figure 2*

### Prevalence of fake medicines in Malaysia

- **According to MoH studies, 5.2% of medicines sold over the counter are fake.**
- **In 2006, Pfizer (Malaysia) found that 4.8% of its proprietary drugs (Viagra, Norvasc and Lipitor) were fake.**
- **Malaysian pharmacy enforcement officers found 362 fake medicines batches amongst 11,934 seized (3.03%).**
- **In 2005, a study by the Pharmaceutical Association of Malaysia found 5% of prescription medicines were fake, including eye drops, inhalers, and medication for erectile dysfunction (where incidence was 8.5%).**
- **In 2007, fake medicines totaling a value of US$10.6m were seized in Malaysia, an increase of 40% since 2004**
- **A 2008 report by Espicom found that "counterfeiting...makes up an estimated 5 %" of the pharmaceutical market in Malaysia**

### Prevalence of fake medicines in a sample of lower-income Asian countries

- **In 2006 a study throughout Laos, Myanmar, Vietnam, Cambodia found that 68% of artesunate (anti-malaria) drugs did not contain the correct amount of active ingredient (Alter Hall, 2006).**
- **27% of anti-malarial drugs tested in Cambodia in 2006 were found to have incorrect levels of active ingredient (Lon, 2006).**
- **22% of sampled antibiotics and anti-malarial drugs sampled in Laos in 2004 had incorrect levels of active ingredient.**
- **7% of a sample of anti-malarial, TB and antibiotic drugs tested in major Indian cities failed quality testing (Bate, 2012).**
- **The Federation of Indian Chambers of Commerce claim that 15-20% of medicines on sale in India are fake[7], although the government claims the rate is 0.04% based on its own research.**

faking medicines far outweigh the risks. Manufacturers and purveyors of fake medicines can make large profits while running minimal risks of detection. The chance of a successful criminal prosecution or civil action is even less likely.

Faking medicines has become a relatively low-risk activity as a result of some major deficiencies in the legal systems of the worst affected countries:

- Weak or absent rule of law, wherein fake medicine producers may be able to bribe law-enforcement officials to turn a blind eye, or where the drug regulation agency becomes corrupted.
- Inability of brand owners to protect their trademarks due to inadequate, unenforceable or absent legislation .
- Lack of adequate civil liability laws, which would allow consumers harmed by fake products to sue the perpetrator for damages – thereby discouraging such activity.
- A lack of a global consensus as to what legally constitutes a fake medicine, making it easier to exploit global supply chains, parts of which may pass through locations where legislation is weak and /or poorly enforced.

## Different kinds of products

Fake medicines can include both on-patent branded medicines, and common and cheap generic medicines, such as analgesics, anti-infectives and even vitamin pills.

Generic medicines are particularly popular targets in poorer Asian countries: the top five most faked medicines in Indonesia and the Philippines are all common and inexpensive medicines that have long seen their patents expire (Figure 3).

*Figure 3: Top five faked medicines in Indonesia and Philippines*

| Rank | Indonesia | | Philippines | |
|---|---|---|---|---|
| | **Drug** | **Class** | **Drug** | **Class** |
| **1** | Ponstan 500mg | Painkiller | Adalat Gits 30mg tablet | Anti-hypertensive |
| **2** | Fansidar tablet | Anti-malarial | Ventolin Expectorant syrup | Anti-asthma |
| **3** | Dextamine tablet | Antihistamine | Ponstan 500mg | Painkiller |
| **4** | Glibenclamide tablet | Anti-diabetic | Diatabs reformulated | Anti-diarrhoeal |
| **5** | Ponstan 250mg capsule | Painkiller | Propan syrup | Vitamins |

*Source: Cockburn et al, 2005; National Agency of food and Drug Control, Indonesia, 2007*[8]

This suggests that counterfeiters targeting Asian countries prefer to exploit therapeutic classes for which there is a large potential market, rather than exploiting the higher price differentials that could be derived by faking on-patent medicines (which tend to have smaller markets).

Although Malaysia has relatively low rates of fake medicines compared to certain ASEAN neighbours, there are some concerns about the quality and integrity of the many traditional medicines that are widely sold in the country.

- A study published in 2005 found that 14% of tested Smilax Luzonensis (more commonly known as Akarbanar) contained 0.51–1.23ppm mercury, thereby contravening quality requirements for traditional medicines in Malaysia[9].

*The globalisation of pharmaceutical supply chains has created new opportunities for the fake medicines trade*

There is an increasing body of evidence to suggest that the two main fake medicine producing countries are India and China.

- In 2012, the Health Director General in Malaysia advised the public to stop buying the traditional product Mymen Plus after it was found to contain a scheduled poison[10].

## Where do fake medicines originate?

Given the complexity of global pharmaceutical supply chains and the increasing technical skill of counterfeiters, it is difficult for researchers and authorities to determine the exact origins of a fake product. There is an increasing body of evidence to suggest that the two main fake medicine producing countries are India and China. India, home to up to 16,000 small drug producers, appears in particular to be a major production area:

- According to 2005 TAXUD statistics released by the European Commission, 75% of global cases of counterfeiting originate from India, 7% from Egypt and 5% from China[11].
- A 2004 survey of medicines on sale at a large bazaar in New Delhi found that only 7.5% were genuine. A report in an Indian newspaper said that fakes are freely sold to "exporters who sell them to unsuspecting health administrators in Sub-Saharan Africa, who receive some of the millions in aid money"[12].
- In 2008 the Nigerian government banned imports from 22 Indian pharmaceutical firms[13] and even set up an office for their regulator (NAFDAC) in India in order to improve the quality of the drug supply.

China is also implicated as a major production source for fake medicines:

### Negative impacts of fake medicines

- **Increased mortality and morbidity as sick people are not treated correctly or actively harmed by toxic products.**
- **Development of drug resistance, particularly for anti-malarials, anti-infectives and anti-retrovirals.**
- **Adverse effects from incorrect active ingredients.**
- **Loss of confidence in health systems and health workers.**
- **Economic loss for patients and health systems.**
- **Undermining of drug research and development as innovator drugs compete with fake versions.**
- **Crowding out of legitimate drug manufacturers, who have made costly investments in bringing their plants up to Good Manufacturing Practice**
- **A general erosion of confidence in health systems and the medicines supply, making it less likely that the sick will come forward for treatment**

- In 2008, concerns about the quality of China's drug manufacturing industry and its potential impact on US patients led the US Federal Drug Administration to establish its first overseas office in Beijing.[14]

- In 2009, Nigeria's NAFDAC stated that that a large consignment of fake generic anti-malarial pharmaceuticals labelled "Made in India" were, in fact, found to have been produced in China.[15]

- A 2008 investigation into the provenance of a range of fake anti-malarial products circulating in South East Asia found definitive proof that many samples originated from the China/SE Asia border. This was determined after forensic analysis found pollen samples from plants that grow only this region.[16]

There is also evidence that counterfeiters are taking advantage of the minimal customs bureaucracy of free trade zones such as Dubai, Mauritius, Panama and Hong Kong to penetrate legitimate pharmaceutical supply chains. According to an investigation by the New York Times, nearly a third of all counterfeit drugs confiscated in Europe in 2006 transited via the United Arab Emirates[17].

## The costs of fake medicines

The main risk of fake medicines is to individual health. At their most dangerous, fake medicines can contain toxic materials that are actively harmful to health. For example, 80 patients died in the US in 2008 after taking Chinese manufactured Heparin (an anti-coagulant) that had been contaminated with over-sulphated chondroitin sulphate.

Other examples of toxic contaminants found in fake medicines include heavy metals such as lead or arsenic, rat poison, road paint, anti-freeze and floor wax.[18]

There are also wider public health risks to fake medicines. Drug resistance can occur when a patient suffering from a disease caused by a micro-organism or parasite, such as malaria or tuberculosis) takes a fake with a sub-therapeutic amount of active ingredient. The dose will not be enough to kill the micro-organism, which will then learn how to outwit the drug, resulting in drug-resistant strains of disease.

This is currently an acute problem with tuberculosis in sub Saharan Africa, and is a worsening problem in South East Asia.[19]

Drug resistant forms of malarial parasite have also rendered all classes of anti-malarials next to useless in treating the disease in many parts of the world, with the exception of newer artemisinin-based treatments. There are now concerns that these too will be outwitted by malaria parasites as a result of the high prevalence of fakes circulating in South East Asia. In 2012 a team of researchers wrote a report in The Lancet, showing evidence of drug resistance to artemesinin therapies on the border of Thailand and Myanmar, increasing concern that resistance could soon spread to India, and subsequently Africa[20].

## What is being done at the international level?

It is clear that fake medicines are not only a growing menace in the poorer Asian countries, but that they are penetrating the supply chain even in relatively tightly regulated markets such as Malaysia.

Given that fake medicines have thrived

Toxic contaminants found in fake medicines include heavy metals such as lead or arsenic, rat poison, road paint, anti-freeze and floor wax.

on the globalisation of pharmaceutical supply chains, many have looked to the UN's specialist health agency, the World Health Organization, to provide the appropriate global regulatory and legal framework to member states, in particular an internationally recognised legal definition for fake medicines. This is a vital precondition of concerted international action to combat a problem that involves perpetrators moving fake goods across multiple borders and operating in multiple jurisdictions.

However, it has so far been impossible for the international community to agree on a definition for fake medicines. The WHO's attempt at its International Medical Products Anti-Counterfeiting Taskforce (IMPACT) was ultimately derailed at a meeting of the World Health Assembly in 2010 by India, on the back of ill-founded fears that an overly restrictive definition would be used to hinder its powerful generics industry – even though the future profitability of the Indian generics industry is entirely dependent on maintaining a reputation for producing safe, high quality medicines.

In 2010 the Council of Europe ratified the MEDICRIME convention, to which EU member states and a number of former Soviet states are signatories. While this treaty provides signatories with useful clarity over what legally constitutes a fake medicine, it is unlikely that a European-led convention will attract signatories from Asia and other emerging markets where the main locus of the problem lies.

There are few regional Asian initiatives of note, with the exception of Interpol activities and ASEAN attempts to harmonise medical systems in order to promote greater trade in health services between members. But ASEAN's efforts have been hampered by high rates of counterfeit medical products, particularly in countries like Thailand and Cambodia.[21]

Increasing numbers of health policy experts and legal scholars are now pushing for an international treaty in order to coordinate global action against the scourge of fake medicines. According to its proponents, "the lack of a treaty means there is generally no agreement on which medicines are wrongful or criminal; no requirement for police to cooperate across borders in carrying out international investigations; and no requirement for prosecutors to share evidence or to respond to extradition requests to bring perpetrators to justice."[22] As an example, Indonesia does not identify medical counterfeiting as a specific crime, which hampers the ability of enforcement officials to seize fake products and proceed against perpetrators.

Indonesia does not identify medical counterfeiting as a specific crime, which hampers the ability of enforcement officials to seize fake products and proceed against perpetrators.

An international treaty would correct such problems by providing to signatory countries an agreed international definition for the various kinds of fake medicines; define new public health crimes in international law regarding fake medicine manufacture and trade; and provide new resources for strengthening regulatory capacity in countries where regulation is weakest.

A treaty would provide an important framework to begin addressing the problem of fake medicines, but it is clearly many years off given the divergent industrial interests of emerging and developed economies. Further, it will only be as effective as the ability of signatory countries to enforce regulations, minimise official corruption and uphold the rule of law – an ability that is lacking in many Asian countries (particularly India, Pakistan, Cambodia,

Vietnam, Philippines and Thailand).[23] There is also the risk that a treaty might add further layers of bureaucracy to the process of drug approval, potentially delaying market access to innovative therapies.

## The limits of regulation

Most academic and NGO commentators on the problem of fake medicines typically prescribe a mixture of stronger regulation, harsher criminal penalties, and an increase of enforcement activities against individual perpetrators. Many countries in Asia are indeed increasing regulatory capacity and redrafting penal codes to further criminalise the fake medicines trade – even introducing the death penalty, in the case of China, India and the United Arab Emirates. Governments are also stepping up enforcement, with China arresting 1,900 people in August 2012, for instance.[24]

In countries where the rule of law is weak, the creation of new regulatory layers and tougher criminal sanctions may be counterproductive, as new powers for regulators create opportunities for bribery and corruption. Major corruption scandals within drug regulatory bodies occurred in Nigeria in 2000 and Italy in 2008, while in 2012 the Indian Central Drugs Standard Control Organisation was found to be colluding with both local and multinational pharmaceutical companies over the approval of drugs in the country.[25]

- To be effective, stiffer criminal penalties depend on an efficient and fair rule of law, something which does not exist in many Asian countries, particularly the poorer ones which have the greatest problem.
- Stronger criminal penalties will likely drive activities further into the hands of organised criminal cells and will also likely result in further corruption, as the criminal cells seek to infiltrate law-enforcement agencies. The fake medicines trade is already showing worrying signs of mafiaisation, with organised crime groups such as Chinese triads and Mexican drug gangs all becoming implicated in the trade over the past decade. Increasing evidence also implicates the involvement of Hezbollah and al Qaeda.
- The increase in seizures by Interpol and others in recent years is more a symptom of - rather than a solution to - the problem. They do nothing to address the more deep-seated origins of the problem, as has been amply demonstrated by the failure of similar strategies over the last 50 years with illegal narcotics.

More effective solutions must address its fundamental cause, which revolve around the inability of legitimate manufacturers to protect the integrity of their brands. Legal reforms can go some way towards addressing these problems, as can innovative uses of technology. These are discussed in the second of this two part briefing paper.

### About the Authors

Philip Stevens is Executive Director of Emerging Markets Health Network

Dr Helmy Haja Mydin is a Fellow at the Institute for Democracy and Economic Affairs (IDEAS) Malaysia.

Both can be contacted at **info@emhn.org**

the creation of new regulatory layers and tougher criminal sanctions may be counterproductive, as new powers for regulators create opportunities for bribery and corruption.

**EMHN** is a project of Malaysia's **Institute for Democracy and Economic Affairs (IDEAS)** that aims to help emerging markets address their health challenges by exploring the potential of markets and the private sector. **EMHN** works with its network of scholars, think tanks and thought leaders to ensure this perspective is heard in policy debates in Asia, Latin America and Africa. Examples of **EMHN** activities include:

- Coordinating the writing and dissemination of policy papers, monographs and opinion editorials
- Conducting public seminars and events
- Providing commentary to the media on topical health policy issues

IDEAS
Institute for Democracy and Economic Affairs

## References

[1] http://www.oecd.org/industry/industryandglobalisation/oecdprojectoncounterfeitingandpiracy.htm

[2] http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf

[3] http://www.psi-inc.org/incidentTrends.cfm

[4] http://www.who.int/mediacentre/factsheets/fs275/en/

[5] http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050032

[6] http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index1.html

[7] http://zeenews.india.com/exclusive/15-20-of-medicines-sold-in-india-are-fake-ficci_5418.html

[8] National Agency of Food and Drug Control, "Combating counterfeit drugs in Indonesia", presentation to first ASEAN-China Conference on Combating Counterfeit Medical Products, Jakarta, 13-15 November 2007

[9] H.H. Ang& K.L. Lee (2005), "Analysis of mercury in Malaysian herbal preparations",Journal of Medicine and Biomedical Research, 4(1): 31-36

[10] http://www.intelasia.net/malaysia-bans-two-traditional-medicinal-products-237551

[11] European Commission Taxation and Custom Union (TAXUD) statistics, 2005.

[12] "Fake drug industry operates openly", LiveMint, 13th May 2007 http://www.livemint.com/2007/04/30000718/Fake-drug-industry-operates-op.html

[13] http://allafrica.com/stories/200810220021.html

[14] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OfficeofInternationalPrograms/ucm243677.htm

[15] http://timesofindia.indiatimes.com/business/india-business/Chinese-passing-off-fake-drugs-as-Made-in-India/articleshow/4633377.cms?

[16] Newton et al, (2009), "A Collaborative Epidemiological Investigation into the Criminal Fake Artesunate Trade in South East Asia", PLOS Medicine, February 2008

[17] http://www.nytimes.com/2007/12/17/world/middleeast/17freezone.html

[18] http://www.safemedicines.org/2012/03/no-drugs-at-all-.html

[19] http://www.searo.who.int/LinkFiles/Tuberculosis_Status_paper_MDR_TB_SEARO_2011.pdf

[20] Phyo AP et al. (2012), "Emergence of artemisinin resistant malaria on the western border of Thailand: a longitudinal study.",Lancet

[21] http://prema.or.th/uploads/premanews_detail/75_asean_harmonizationstandardizationbymasonschool.pdf

[22] Attaran et al, (2012), "How to achieve international action on falsified and substandard medicines", British Medical Journal; 345:e7381

[23] http://worldjusticeproject.org/sites/default/files/WJP_Rule_of_Law_Index_2011_Report.pdf

[24] http://www.bbc.co.uk/news/world-asia-china-19144556

[25] http://www.bloomberg.com/news/2012-05-10/indian-drug-regulator-accused-of-corruption-and-collusion.html