Healthy By Law

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“Healthy by law: the missed opportunity to use laws for public health,” *The Lancet* 2012; DOI:10.1016/S0140-6736(11)60069-X.

Law and global health initiatives are fellow travelers, but

- **Health For All (1978)**
  - Universal health insurance laws
  - Health care worker licensing laws
  - Pharmaceutical & medical device regulation laws
- **Tobacco Free Initiative (1998)**
  - Tobacco marketing laws
  - Smoking laws
- **Social Determinants of Health (2011)**
  - Urban land use laws
  - Food content and labeling laws
  - Social welfare & solidarity laws to promote equity
  - Laws for NCD control (tobacco, nutrition and “metabo”)

Good laws are the ultimate global public good for health

- **Laws are free.** Anyone can copy a good law. There is no intellectual property: it is impossible to patent a law.
- **Laws are transparent.** All laws are public. They can be debated by the public and Parliament.
- **Laws support equity**. In countries with a human rights constitution, laws cannot discriminate on age, race, or sex.

BUT THERE IS NO SYSTEMATIC DATABASE OF HEALTH LAWS, SO THESE ADVANTAGES ARE UNREALIZED

The old WHO Digest (now dead)

WHO - International Digest Of Health Legislation

Welcome to the International Digest of Health Legislation (IDHL) on-line database.

The *International Digest of Health Legislation* contains a selection of national and international health legislation. Texts of legislation are summarized in English or mentioned by their title. Where possible, links are provided to other websites that contain full texts of the legislation in question.

The electronic version of the *Digest* supersedes the printed version, which was published from 1948 to 1999. It represents the latest stage in the evolution of a service which began in 1909 with the publication of the first issue of the *Bulletin mensuel de l'Office international d'Hygiène publique*.

This page allows you to query the database:

- By selecting a country
- By selecting a subject
- By selecting a volume
- By selecting an issue
- And by looking for a specific keyword

Last Update: 01 May 2012

By Country | By Subject | By Volume | By Issue | By Keyword | Subject Notes | Home Page | Get Acrobat Reader

Other UN agencies have law libraries

- **ILO** has a library of labor and employment laws (NATLEX)
- **World Bank and IMF** have a library of banking laws (The Global Banking Law Database)
- **WIPO** has a library of patent, trademark and copyright laws (WIPO-LEX)
- **UNODC** has a library of narcotics control laws (The Legal Library)
- **UNESCO** has a library of cultural protection laws (the Database of National Cultural Heritage Laws)
- **IAEA** has a library of atomic energy laws (Nuclear Law Institute)
- **UNOOSA** has a library of laws for outer space (National Space Law Database)

Tobacco

- Because of the FCTC, there are many laws, from complete public smoking bans, to regulations of advertisements and packaging material. **Too many countries to count**.
- **Australia is the best**. Plain paper packaging. This has survived legal challenge, but might not do so well in other countries with constitutionalized freedom of expression.
- **Ireland** proved that indoor smoking bans are not economically ruinous. The pubs didn't go out of business. But don't introduce an indoor smoking ban in winter!
- **Canada** limits advertising to point of sale. Won't do Australian-style packaging though, ironically stating that the gruesome packages are less intrusive than plain paper.
- **Regulate e-cigarettes** or not? Perhaps not: harm reduction is a valid clinical paradigm.
- **Laws on smoking cessation are weak.** Tax credit for smoking cessation programs?

Trans fat

- Trans-fat can effectively be abolished from commercially produced foods and legislation can make this happen.
- **Denmark** has a 2% limit of TFA in processed food. Denmark has seen a 15% drop in HT. Causality open to question. Also there are TFA restrictions in **Turkey, Iceland, California, New York City**.
- **Poland** has reduced subsidy on high fat food. **Finland** did likewise, but transferred the subsidy from dairy to berry farmers, thereby taking away a negative risk factor and replacing it with a positive one.
- Alternatively trans-fatty foods can be mandatorily labeled: **Canada, USA**.
- Require explicit, tobacco-style health warnings? No examples of that yet.
- Make limits on TFA a condition of licensing food establishments? Now you are into health impact assessment: potentially a very far reaching tool that nobody is using yet.

Sodium and Sugar

- Debate as to the NOAEL, or paradoxical clinical benefit (Na<2.3 g/d), is not a reason to avoid prudential legislation on excess consumption. Case in point: alcohol.
- **Finland** limits Na in typically high-salt foods (soups, sauces) and requires high-salt foods to be labeled. Thought to be associated with about a 13% reduction in HT, but causality is open to question. **United Kingdom** has a red/yellow/green light system, and Na intake is down about a gram.
- **Argentina** has legislated lower salt in staple foods (bread, cheeses) and in Buenos Aires, you have to ask for a salt shaker. Consultation was essential to overcome resistance.
- **Mexico** has just passed a tax on sugary drinks. Consultation turned highly acrimonious there.
- **France** has also. **New York City** tried to prhibit big fast food sodas; courts struck it down in case brought by strange bedfellows of the food industry.
- If you have legislated iodine in salt (almost everywhere has) then you are halfway there.
- **Subsidy is a huge problem**, especially for corn-based carbohydrate syrups.

National Comitee for salt reduction and trans fatty acids elimination

- **Ministry of Health**
- **Ministry of Agriculture**
- Ministry of Social Development
- Ministry of Science and Technology
- SENASA , INTI

- **INAL - DENT - CN ONGs**
- **COPAL**
- Universities /Propia
- Food Industry Unions
- FAIPA, ASAGA
- Cooperatives

Modification of the Alimentary law "Argentina libre de trans 2014"

Comunication strategies

Establishment of 4 workgroups related to the food category: 1.Meat and cold cuts, 2.dairy products, 3.bread and biscuits, 4. Soups and canned food

1- Baseline diagnosis

2- negotiation with food industry for the settlement of targets of each group

3-Sign of agreements with the obligation of companies to reduce salt content

4-Evaluation and surveillance

Physical Activity

- Our cities determine our movement. **London** has a congestion charge. Public transport utilization is very much up, so people are walking some.

- **Canada** has a tax credit for youth activities, including sport. Also tax exempts bicycles, but only if they cost under $1000, which is silly.

- Overall physical activity laws are unimaginative and lacking. Some ideas:

  – All land use planning is done by zoning. So mandate walking and green space, obviously. Mandate pedestrian walkways. Cairo needs these!

  – By the way, you can restrict fast food restaurants at the same time. Today's McDonald's is yesterday's Broad Street Pump.

Continuum of care: dx to tx

- Intangible, but very important: most HT and pre-diabetes is undetected. Primary prevention is both cheaper and more effective than secondary prevention (so vastly more cost-effective).

- **Japan** has the fascinating "Metabo Law". Insurers and employers organize mandatory yearly check-ups. Persons who are obese (by BMI) or have underlying hypertensionare provided help (consultation with dietitian, exercise regimen and follow up calls).

- Japan's obesity rate is 2%, an order of magnitude better than its peers.

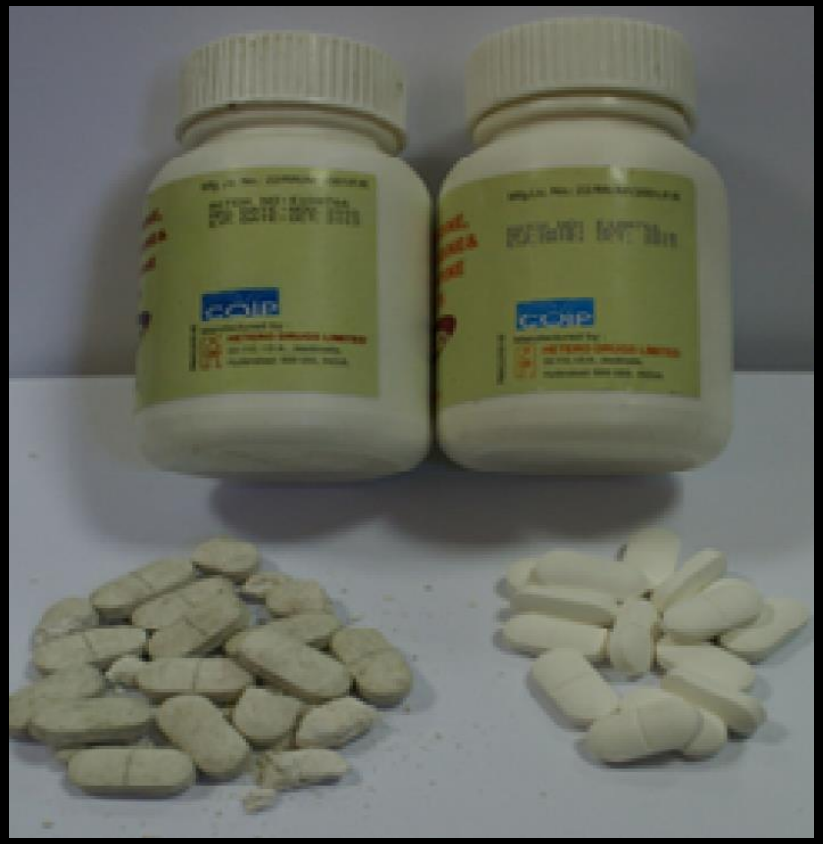
Government process improvements

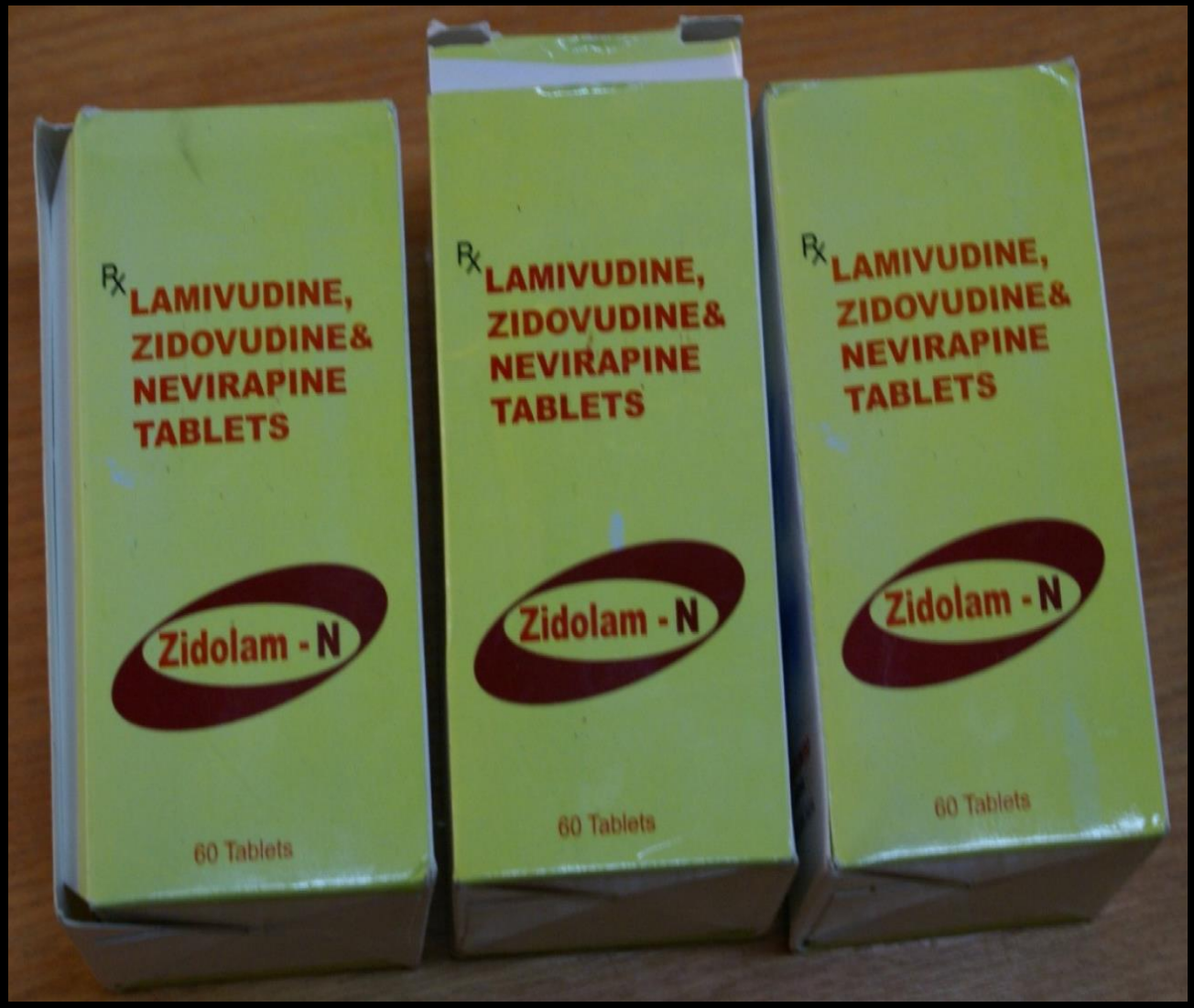
- There should be **health impact assessment laws**, similar to environmental impact assessment laws that are triggered with permitting decisions: permit issuance is linked to impact mitigation. No country has a serious HIA law, and what people call HIA is a terrible misnomer.

- There should be legislated **transparency** in guideline and policy-setting. The **US** has this to an extent with FDA panels being open. **Brazil** has a mandatory dialogue between the Minister and stakeholders.

- And, unfortunately, we have crime to deal with….

Fake AIDS meds bought by Medecins Sans Frontieres: Nairobi, Kenya, 2011.





AUTHENTIC COUNTERFEIT

NLA.13 Abstract (Atorvastatin Generics Study) Published in the *Journal of Clinical Lipidology*, 2013

individualized maximum tolerated dose of lomitapide during the 52 week Safety Phase. During this time, modifications to concomitant LLTs, including apheresis, were permitted. Safety assessments included LFT monitoring and liver fat evaluation by NMRS.

Results: Of the 29 patients enrolled, 18 (62%) were receiving either plasma or LDL apheresis; 23 patients (13 on apheresis) completed the week 26 efficacy evaluation and the entire 78 week study. Baseline LDL-C levels in patients on apheresis and patients not on apheresis were 326 ± 108 mg/dL vs. 355 ± 125 mg/dL, respectively. LDL-C levels were reduced by 48% at week 26 in patients undergoing apheresis treatment and by 55% in patients not on apheresis treatment ($P = 0.54$). Similarly, no differences were observed for ApoB, total cholesterol, triglycerides or other lipoprotein parameters. During the 52 week Safety Phase, 6/13 patients (46%) had a permanent change to their apheresis regimens; 3 stopped treatment and 3 decreased its frequency. All 3 patients who stopped apheresis had >50% reduction in LDL-C at week 78 compared to baseline (-61%, -64%, and -71% respectively).

Conclusions: Lomitapide significantly reduced LDL-C and other ApoB-containing lipoprotein in patients with HoFH, and the level of efficacy appeared to be independent of whether patients were or were not receiving apheresis.

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Atorvastatin Generics Obtained from Multiple Sources Worldwide Contain a Methylated Impurity that Reduces Their HMG-CoA Reductase Inhibitory Effects

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Lead Author's Disclosures: None

Study Funding: None

Synopsis: Atorvastatin is an HMG-CoA reductase (HMGR) inhibitor indicated for the treatment of hypercholesterolemia (HC). Originally approved in crystalline form, numerous non-crystalline (polymorphic) versions of atorvastatin, in generic form, are now available worldwide. Differences in manufacturing practices may result in the production of generic forms with reduced efficacy and safety due to potential impurities. The availability of quality generic medications for HC treatment is a global health priority.

Purpose: In this study, we performed detailed chemical analyses on generic versions of atorvastatin obtained from more than 30 manufacturers worldwide and compared to a standard (crystalline) reference (SR) as well as the branded form of atorvastatin (Lipitor®). A methyl ester atorvastatin impurity, found in high levels in the generic formulations, was isolated and tested for its ability to inhibit HMGR activity.

Methods: The elemental composition of 36 different atorvastatin generics, obtained from 15 countries, was analyzed by liquid chromatography-mass spectrometry (LC-MS). UV-Vis spectroscopy was used to measure the in vitro effects of various forms of atorvastatin, including the SR and a common methyl ester impurity identified by LC-MS, on the specific activity of HMGR. Enzyme activity was determined by monitoring the rate of NADPH oxidation by the catalytic subunit of HMGR in the presence of the substrate HMG-CoA.

Results: All of the generic atorvastatin formulations tested in this study were shown, by LC-MS analysis, to contain reproducibly elevated levels of a specific methyl ester impurity (16.0 ± 6.5% by relative mass signal), which was observed at only trace levels (<1.5%) in the crystalline SR and Lipitor® preparations. The methyl ester impurity did not inhibit HMGR even at suprapharmacologic levels (200 nM). By contrast, SR and Lipitor® significantly inhibited HMGR with an IC50 of ~40 nM. A separate SR lot stored at room temperature (RT) for 10 years also did not show impurities or any loss of HMGR activity. The methyl ester impurity was reproduced in SR samples only after exposing it to an alkylating solvent for 10 weeks at RT or higher.

Conclusions: A methylated atorvastatin impurity was highly conserved in generic atorvastatin formulations collected from various manufacturers and countries. This impurity was found at relatively high levels and was shown to have no inhibitory effects on HMGR enzyme activity. The presence of this impurity in widely-available versions of generic atorvastatin may compromise global efforts towards the effective management of HC among patients with cardiovascular risk.

Visceral Obesity, Metabolic Syndrome and Atherosclerosis

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The ACT II Study: Influence of BMI on Serum Lipids

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Lead Author's Disclosures: Dr. Lautsch is employed by Merck & Co.

Study Funding: This study was supported by Merck & Co.

Synopsis: Both dyslipidemia and obesity are important determinants for cardiovascular disease. The association of BMI with lipid parameters for statin-treated patients is unknown.

Purpose: We therefore aimed to identify associations of BMI and serum lipids as well as their potential relevance for pharmacological treatment.

Methods: The non-interventional ACT II study [www.clinicaltrials.gov NCT 01381679] examined 1682 high cardiovascular risk, statin treated patients in an outpatient setting who failed to achieve LDL-C targets. Lipid lowering

R.P. Mason, *et al.*, *J. Clin. Lipidol.*, 2013; **7(3)**:287.

Some globally-traded medicines are poorly regulated

- India's drug regulator (CDSCO) is governed by obsolete laws dating form 1940 and 1945.

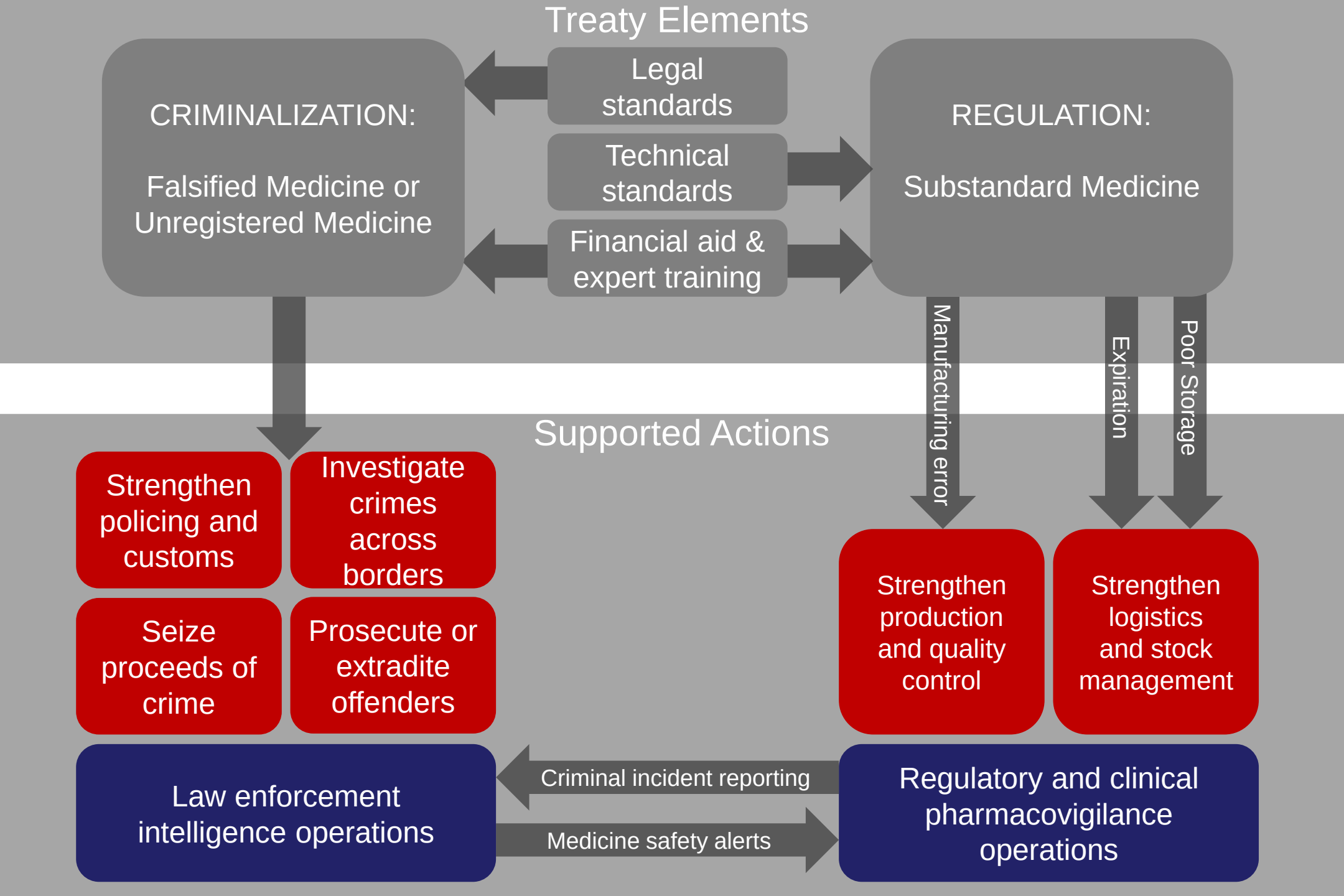
- CDSCO only has legal jurisdiction over "new drugs", in the sense of novel therapeutics, and has no authority whatsoever over new versions of old drugs: i.e. most generic medicines (*Rules*, s. 122E)

- Since new FDCs (polypills) are considered "new drugs" CDSCO has oversight, but only for four years. Thereafter all jurisdiction reverts to the states. However, the states appear ineffective at licensing facilities, monitoring products and prosecuting violations.

Number of samples tested and enforcement actions taken by State Drugs Controller during 2011-12

S.No.	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	No. of prosecution launched	No. of persons arrested	Approximate value of drugs seized (In Lakhs.)
1	Andhra Pradesh	4758	22	2	Nil	Nil	Nil
2	Arunachal Pradesh	95	2	Nil	Nil	Nil	Nil
3	Assam	315	25	Nil	Nil	Nil	Nil
4	Bihar	711	8	Nil	24	32	5.69
5	Goa	765	25	Nil	Nil	Nil	Nil
6	Gujarat	2874	186	64	6	Nil	137.94
7	Haryana	1669	32	12	3	2	25.00
8	Himachal Pradesh	1470	32	0	1	0	16.00
9	Jammu & Kashmir	1940	133	5	1	Nil	37.22
10	Karnataka	5268	159	2	3	Nil	13.77
11	Kerala	3904	202	Nil	Nil	Nil	Nil
12	Madhya Pradesh	2617	104	Nil	Nil	Nil	Nil
13	Maharashtra	6928	521	19	7	Nil	258.27
14	Manipur*	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya	68	Nil	Nil	Nil	Nil	Nil
16	Mizoram	71	Nil	Nil	Nil	Nil	Nil
17	Nagaland	12	Nil	Nil	Nil	Nil	Nil
18	Orissa	2910	54	Nil	Nil	Nil	Nil
19	Punjab	3031	41	1	2	Nil	166.37
20	Rajasthan	1605	128	Nil	13	Nil	5.74
21	Sikkim	26	1	Nil	Nil	Nil	Nil
22	Tamilnadu	4110	298	4	4	Nil	Nil
23	Tripura	185	8	Nil	Nil	Nil	Nil
24	Uttar Pradesh	1328	152	11	136	91	317.00
25	West Bengal#	687	18	3	5	5	10.00
26	Pondicherry	48	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar Island	Nil	Nil	Nil	Nil	Nil	Nil
28	Chandigarh	79	6	Nil	Nil	Nil	Nil
29	Delhi	283	13	9	5	11	0.39
30	Dadra & Nagar Haveli	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	89	1	Nil	Nil	Nil	Nil
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgarh	36	9	Nil	Nil	Nil	3.28
34	Jharkhand	20	3	Nil	1	Nil	0.80
35	Uttaranchal	180	3	1	Nil	Nil	Nil
	Total	**48082**	**2186**	**133**	**211**	**141**	**997.47**

#*West Bengal has reported 11 cases of Spurious/Misbranded/Adultrated ISM (Indian Systems of Medicine) drugs, in addition to the above cases.


Treaty Elements
CRIMINALIZATION:
Falsified Medicine or Unregistered Medicine
Legal standards
Technical standards
Financial aid & expert training
REGULATION:
Substandard Medicine
Manufacturing error
Expiration
Poor Storage
Supported Actions
Strengthen policing and customs
Investigate crimes across borders
Seize proceeds of crime
Prosecute or extradite offenders
Strengthen production and quality control
Strengthen logistics and stock management
Law enforcement intelligence operations
Criminal incident reporting
Medicine safety alerts
Regulatory and clinical pharmacovigilance operations

Further questions:
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