

# Tuja predstavništva farmacevtskih družb v Sloveniji in etika v farmacevtski industriji

Matej Linke MBA, mag.farm.

# vozni red

- Tuja farmacevtska podjetja v SLO
- Poslovanje
- Organiziranost
- Etika
  - Splošna podoba
  - Zakonska podlaga
  - Kodeksi

# Tuja farmacevtska predstavništva v sloveniji

- Farmacevtski trg v Sloveniji presega 500 mio €
- Tuje farmacevtske družbe predstavljajo 1/2 trga
- V SLO je s svojimi zdravili prisotnih več kot 70 tujih farmacevtskih družb
- Načini organiziranosti in poslovanja so različni
- Največje so povezane v gospodarsko interesno združenje FORUM

# Tuja farmacevtska predstavništva v sloveniji



**Abbott Laboratories d.o.o.**  
Dolenjska 242c, 1000  
Ljubljana  
T: (01) 236 31 60  
www.abbott.com



**Alcon, farmacevtske storitve d.o.o.**  
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T: (01) 422 52 80  
www.alcon.com



**Amgen zdravila d.o.o.**  
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Ljubljana  
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www.amgen.com



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Titova 8, 2000 Maribor  
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www.lundbeck.com



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www.merck.com



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www.novonordisk.si



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Letališka 3C, 1000 Ljubljana  
T: (01) 521 14 00  
www.pfizer.si



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Ljubljana  
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www.boehringer-ingelheim.com



**Celgene International**  
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Kržičeva 7, 1000 Ljubljana  
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www.celgene.com



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Ljubljana  
T: (01) 569 28 11  
www.grunenthal.com



**Roche farmacevtska družba d.o.o.**  
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Ljubljana  
T: (01) 360 26 00  
www.roche.si



**sanofi-aventis d.o.o.**  
Dunajska 119, 1000 Ljubljana  
T: (01) 560 48 00  
www.sanofi-aventis.com



**Servier Pharma d.o.o.**  
Pot k sejmišču 33, 1231  
Ljubljana-Črnuče  
T: (01) 563 48 11  
www.servier.com



**GlaxoSmithKline d.o.o.**  
Knezov Štradon 90, 1000  
Ljubljana  
T: (01) 280 25 00  
www.gsk.com



**Janssen, farmacevtski del, J&J d.o.o.**  
Šmartinska 53, 1000 Ljubljana  
T: (01) 401 18 30  
www.janssen-cilag.si



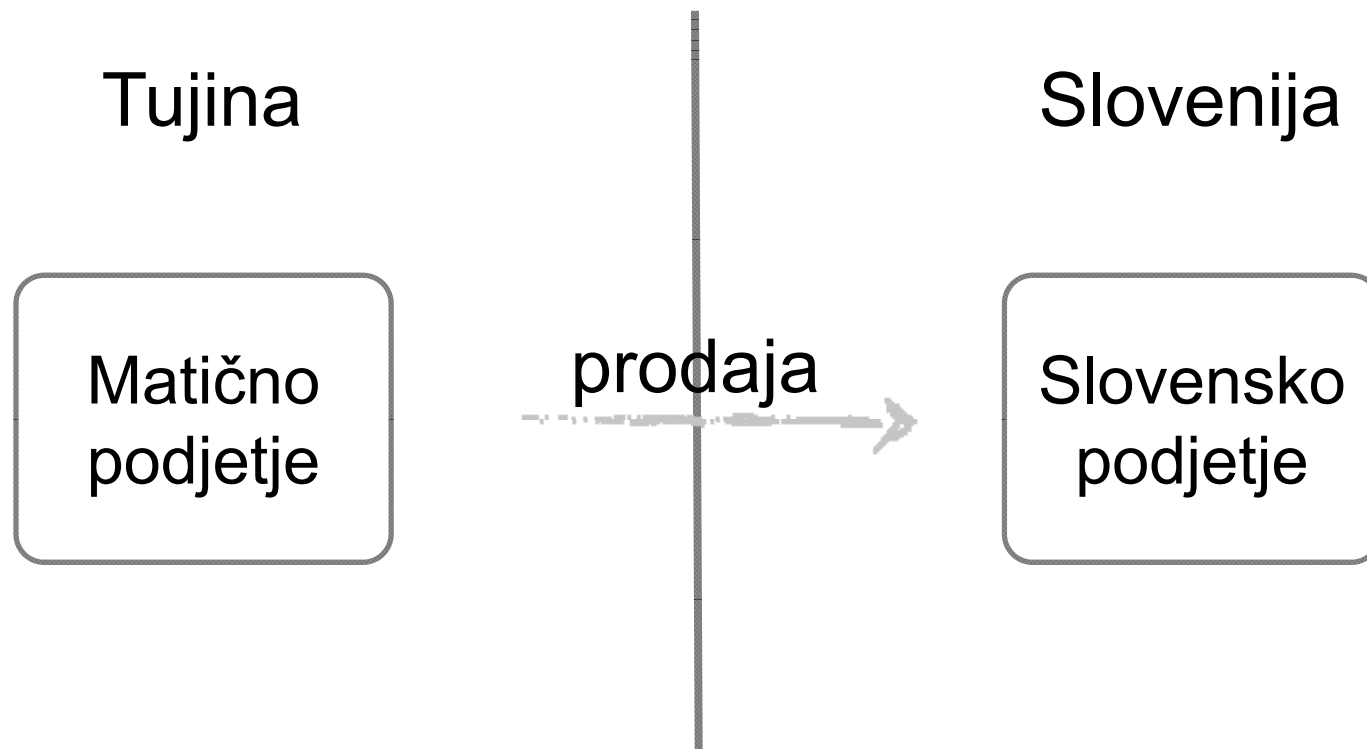
**Eli Lilly farmacevtska družba, d.o.o.**  
Brnčičeva 41g, 1000  
Ljubljana  
T: (01) 580 00 10  
www.lilly.com

<http://www.firdpc.com/>

# Tuja farmacevtska predstavništva način poslovanja

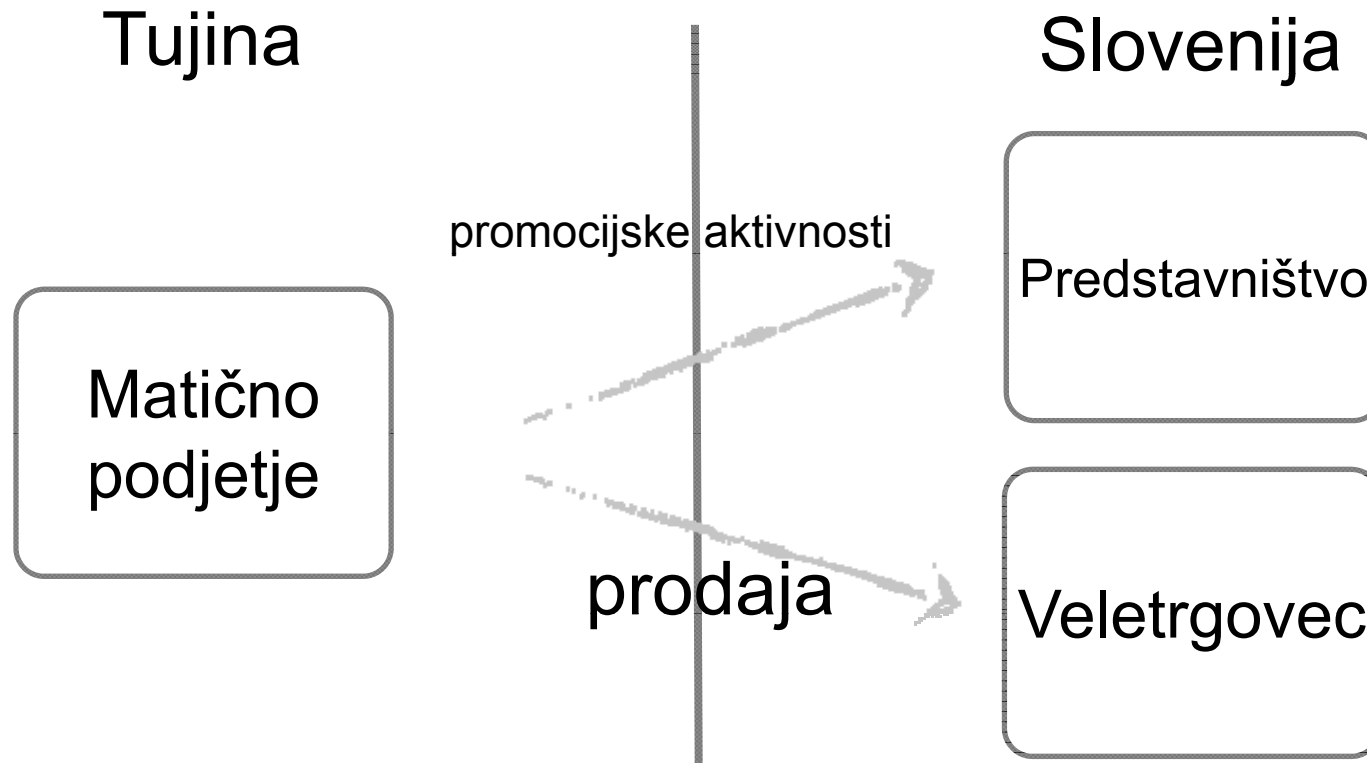
- Zastopništvo (ekskluzivno zastopništvo)
- Podružnica/predstavništvo
- Podjetje za trženje in promocijo
- Prodajno podjetje

# Tuja farmacevtska predstavništva zastopništvo



Podelitev pravice za trženje/prodajo

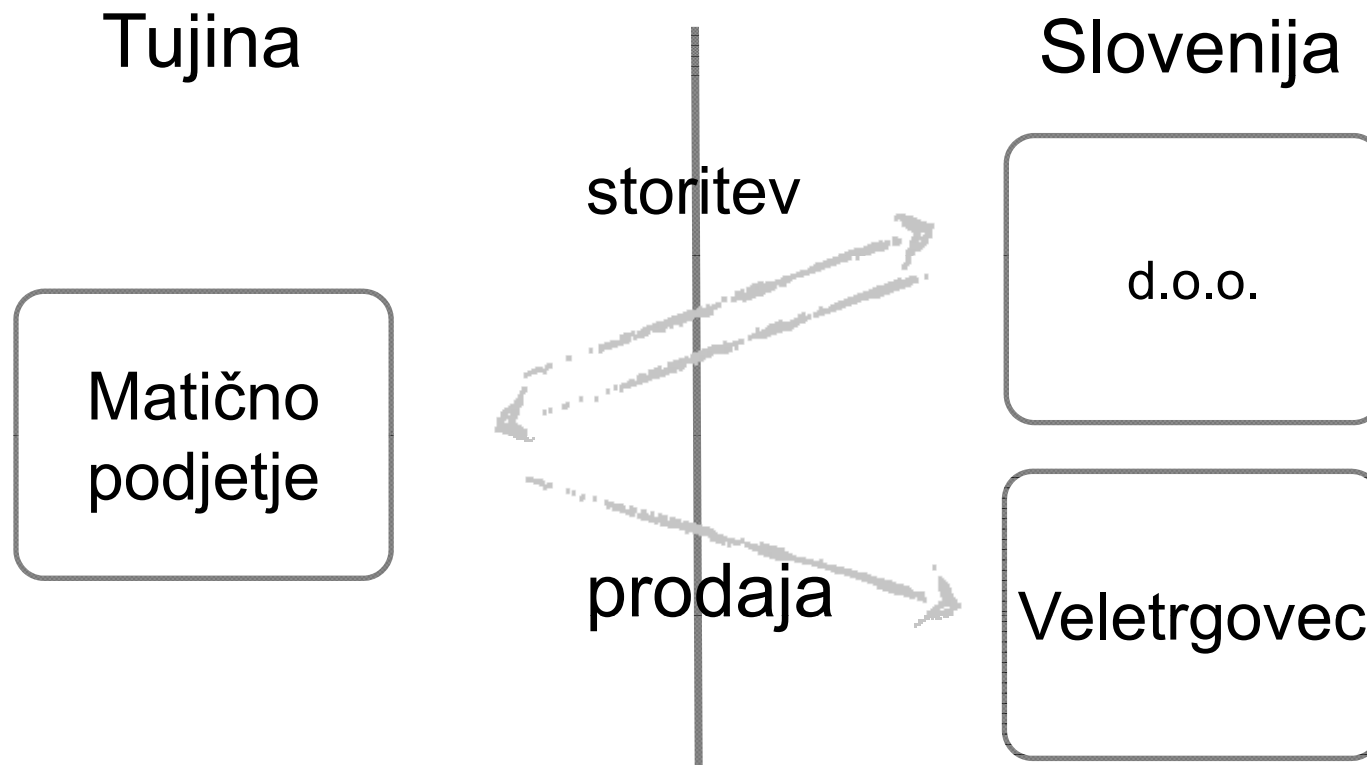
# Tuja farmacevtska predstavništva predstavništvo



**Zastopanje matičnega podjetja v državi**

(raziskava trga, registracije, ... vendar brez prodajne komponente)

# Tuja farmacevtska predstavništva podjetje za trženje in promocijo

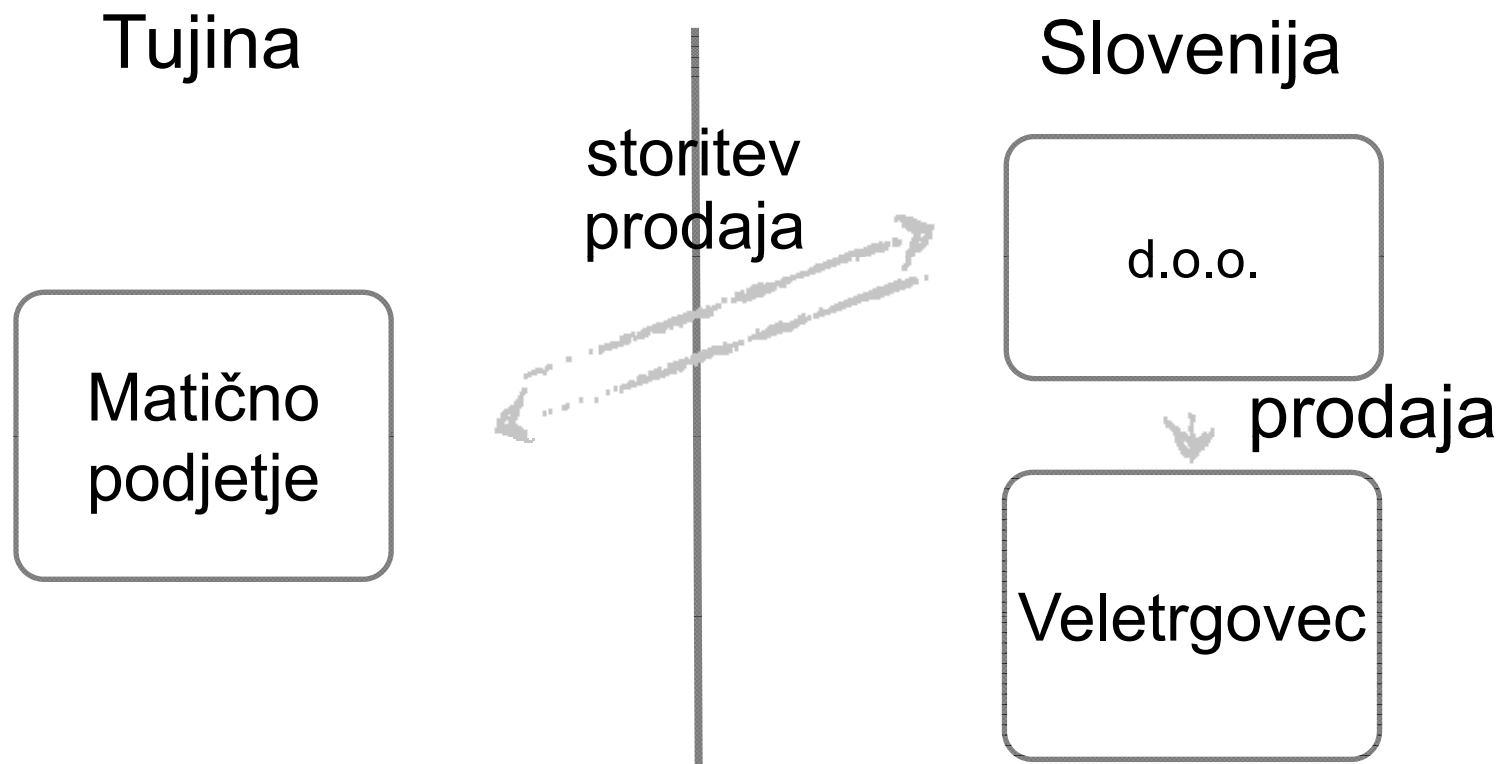


## Storitev trženja za matično podjetje

(trženje, raziskava trga, registracije, ... brez prodajne komponente)



# Tuja farmacevtska predstavništva prodajno podjetje



Celostna storitev za matično podjetje  
(sistem transfernih cen)



# Tuja farmacevtska predstavništva organiziranost

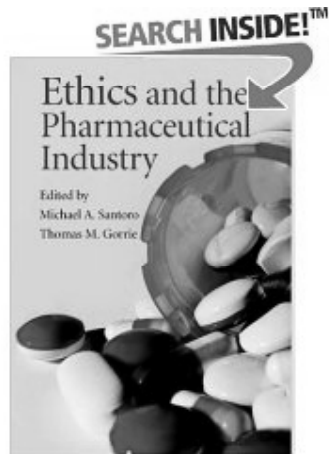
- Pradaja in marketing (S&M)
- Poslovne enote (BU)
- Klasterska organiziranost



# Tuja farmacevtska predstavništva organiziranost 2

- ODDELKI:
  - Regulativa
  - Prodajni oddelek
  - Medicinski oddelek
  - Oddelek marketinga
  - HR
  - Logistika
  - Finance
  - IT

# Etika v farmacevtski industriji



- ZAKAJ JE POMEMBNA?

# RAZLIKA V PROMOCIJI AMERIKA vs. EUROPA



# Etika v farmacevtski industriji

## Pharma industry tops government fraud table in USA

SHARE   

WORLD NEWS | DECEMBER 20, 2010

KEVIN GROGAN

The drug industry has now become the biggest defrauder of the US government, surpassing defence, the long-time leader.

That is the claim of a study from the influential US consumer group Public Citizen, which found that pharmaceutical cases accounted for at least 25% of all federal False Claims Act payouts over the past decade, compared with 11% by the defence industry. The analysis looked at all major pharmaceutical company civil and criminal settlements on state and federal levels since 1991.

Of the 165 drugmaker settlements, comprising \$19.8 billion in penalties during the past 20 years, 73% of the number (121) and 75% of the dollar amount (\$14.8 billion) have occurred during the past five years. Most of them involve off-label promotion and purposely overcharging programmes such as Medicaid and Medicare.



The study also found that more than a half of the industry's fines were paid by four companies - GlaxoSmithKline, Pfizer, Eli Lilly and Schering-Plough - and they accounted for more than half of all financial penalties over the past two decades, paying \$10.50 billion in fines collectively. The two largest fines ever assessed by the US government against any companies were against Lilly (\$515 million) and Pfizer (\$1.2 billion), both in 2009.

The analysis revealed that former employees and other whistleblowers "have been instrumental in bringing to light the most egregious violations". The number of federal settlements arising from whistleblower cases has more than doubled over the past five years, yielding payouts more than two-and-a-half times higher than in the previous 15 years combined. The report also recommends imposing steeper financial penalties and "criminally prosecuting company leadership, including jail sentences, if merited".

### Related Links

[Whistleblowers driven by ethics not cash - i NEJM i study](#)

[Pharma "part of well-organised crime" in US](#)

[Pfizer settles illegal marketing case for massive 2.3 billion](#)

[Lilly pays 1.42 billion to settle Zyprexa litigation](#)

## Pharma "part of well-organised crime" in US

SHARE   

WORLD NEWS | SEPTEMBER 09, 2009

LYNNE TAYLOR

The pharmaceutical industry has made major contributions to the health of the US public, but it must also be considered part of the nation's well-organized crime, says an industry critic.

Last week's \$2.3 billion settlement between Pfizer and the US Justice Department for unlawful prescription drug promotion may sound large, but it is not enough to ensure drug companies will curb their bad behavior - in fact, it just shows there is competition in the pharmaceutical industry, according to Sidney Wolfe, director of US advocacy group Public Citizen's Health Research Group.

Pfizer has broken a record set by Eli Lilly in January for what was then described by the Justice Department as the "largest individual corporate criminal fine" in U.S. history - more than \$500 million in criminal penalties for off-label promotion of Zyprexa (olanzapine), its treatment for psychotic conditions including schizophrenia and bipolar disorder - but now, just seven months later, Pfizer has broken this record with a criminal fine of \$1.2 billion, the largest ever imposed in the US for any matter, he says. The rest of the \$2.3 billion represents civil penalties.

"The US pharmaceutical industry, long one of the most profitable in the country with profits last year of close to \$50 billion, has engaged in an unprecedented amount of criminal activity in the past decade, all aimed at increasing sales, often by illegally promoting drugs for diseases for which evidence that benefits outweigh harm is lacking - also known as illegal off-label promotion," says Dr Wolfe. When doctors are induced, either by being bribed or misled by drug companies, to prescribe drugs for such purposes, there is "a reasonable chance" that the drugs will do more harm than good and patients may be seriously injured or killed by such promotion, he warns.

In addition to Pfizer - which also pleaded guilty to criminal charges for off-label promotion of its anticonvulsant Neurontin (gabapentin) in 2004 - and Lilly, other drug companies found to have engaged in criminal activity in the past 10 years include Abbott, Schering-Plough, AstraZeneca, Purdue and Bayer, says Dr Wolfe. However, he adds: "the ever-escalating fines are unlikely to stop drug companies from continuing to bribe doctors because they represent just a fraction of drug company profits and no one has gone to jail."

Until "corporate titans are forced to fork over a much larger proportion of their illegally-gotten profits and are put behind bars, nothing will change," he concludes.

# Etika v farmacevtski industriji

## AstraZeneca settles Seroquel multi-state marketing probe

11/03/2011

... AstraZeneca is paying out \$68.5 million to settle a lawsuit in the USA ...". AstraZeneca was accused of engaging in unfair and misleading practices when it marketed Seroquel ... that AstraZeneca failed to adequately disclose the potential side effects of Seroquel and withheld negative ... follows a three-year investigation, AstraZeneca will publicly post its payments to physicians ... their products" and to market them "without deception or misleading claims." AstraZeneca is paying out \$68.5 ...

[/Article/11-03-11/AstraZeneca\\_settles\\_Seroquel\\_multi-state\\_marketing\\_probe.aspx](#)

## US Justice Departments investigates pharma for corruption

16/08/2010

in penalties that the industry should be able to absorb easily," Savvas Neophytou of Panmure Gordon ...

[/Article/10-08-](#)

[16/US\\_Justice\\_Departments\\_investigates\\_pharma\\_for\\_corruption.aspx](#)

## Merck & Co pays \$2.3 billion to settle US tax dispute

15/02/2007

... Merck & Co has signed an agreement with the USA's Internal Revenue Service to settle a tax dispute, which will cost the New Jersey-headquartered drugs giant some \$2.3 billion. The company says that this deal "essentially brings to a close" the examination by the IRS into Merck's tax returns from 1993 to 2001 and noted that the \$2.3 billion figure represents its expected "final net cash cost" from the deal, after tax deductions and penalties. However, the IRS ...

[/Article/07-02-15/Merck\\_Co\\_pays\\_2\\_3\\_billion\\_to\\_settle\\_US\\_tax\\_dispute.aspx](#)

## Pharma "part of well-organised crime" in US

09/09/2009

million in criminal penalties for off-label promotion of Zyprexa (olanzapine), its treatment ... for any matter, he says. The rest of the \$2.3 billion represents civil penalties. "The US ...

[/Article/09-09-09/Pharma\\_%e2%80%9cpart\\_of\\_well-organised\\_crime%e2%80%9d\\_in\\_US.aspx](#)

## Pfizer settles illegal marketing case for massive \$2.3 billion

03/09/2009

of dollars". This settlement "represent yet another example of what penalties will be faced when ...

[/Article/09-09-](#)

[03/Pfizer\\_settles\\_illegal\\_marketing\\_case\\_for\\_massive\\_2\\_3\\_billion.aspx](#)

## GSK pays \$750 million over tainted drugs from Puerto Rico

27/10/2010

and subpotent". The other \$150 million is a criminal fine. PD Villarreal, GSK's head of global ...

[/Article/10-10-](#)

[27/GSK\\_pays\\_750\\_million\\_over\\_tainted\\_drugs\\_from\\_Puerto\\_Rico.aspx](#)

## Purdue execs face \$634.5M OxyContin fine

23/07/2007

... A US District judge on Friday accepted a guilty plea and settlement from Purdue Pharma and three of its executives over the marketing of its painkiller OxyContin (extended-release oxycodone), and issued a \$634.5 million fine. This represents approximately 90% of the profits on sales of OxyContin during the period in which the offense took place, papers from the District ... a \$634.5 million fine.

PharmaTimes 7/23/2007 12:00:00 AM 1/13/2013 12:00:00 AM World News 11350

...

[/Article/07-07-23/Purdue\\_execs\\_face\\_634\\_5M\\_OxyContin\\_fine.aspx](#)



# Etika v farmacevtski industriji

## Manufacturing penalties of \$750m for GSK

The US Attorney's Office for the District of Massachusetts has announced that the GlaxoSmithKline (GSK) subsidiary SB Pharmco Puerto Rico will plead guilty to charges relating to the manufacturing and distribution of adulterated drugs and will pay \$750m in penalties.

The faulty products were made between 2001 and 2005 at a GSK plant in Cidra, Puerto Rico that was closed in 2009. They included the blockbuster antidepressant Paxil CR, as well as the anti-nausea medication Kytril (granisetron), the topical anti-infectant Bactroban (mupirocin), and the diabetes drug Avandamet (metformin/rosiglitazone).

The government alleges that SB Pharmco's manufacturing operations failed to ensure that Kytril and Bactroban were free of contamination from microorganisms and that the company's manufacturing process caused Paxil CR's layered tablets to split, meaning at least theoretically that tablets could be distributed that either did not have any therapeutic effect or did not contain the drug's controlled-release mechanism. In addition, the government claims that Avandamet tablets manufactured at the plant did not always contain the correct active ingredients.

The facility also had "longstanding problems of product mix-ups, which caused tablets of one drug type and strength to be commingled with tablets of another drug type and/or strength in the same bottle," according to the Department of Justice.

The penalties that GSK will pay consist of a criminal fine and forfeiture totalling \$150m, as well as a civil settlement of \$600m. The civil settlement, which will be paid to the federal government and the states, resolves charges that the company knowingly caused false claims to be submitted to Medicaid and other government healthcare programs for the adulterated drugs.

The civil settlement resolves a lawsuit filed in federal court in the District of Massachusetts under the whistleblower provisions of the False Claims Act. The whistleblower in this case, a former GSK quality-assurance manager named Cheryl Eckard, will receive about \$96m from the federal share of the settlement.

GSK noted that it had already disclosed a \$750m charge to its second-quarter 2010 earnings in July in connection with the agreement in principle and that it would record no additional charges as a result of the finalised agreement.

"We regret that we operated the Cidra facility in a manner that was inconsistent with current Good Manufacturing Practice requirements and with GSK's commitment to manufacturing quality," PD Villarreal, GSK's Head of Global Litigation, said in a statement.

"GSK worked hard to resolve fully the manufacturing issues at the Cidra facility prior to its closure in 2009 and we are committed to continuous improvement in our manufacturing processes. Our commitment to compliance with cGMP is demonstrated by the fact that we have not received an FDA warning letter at any plant since the Cidra facility was cited in July 2002."

# Etika v farmacevtski industriji

## **Scriptelligence - Russia fines Novo Nordisk \$3 million for violating competition law**

Russia's competition authority, the federal antimonopoly service (FAS), has fined Novo Nordisk Rb86 million (\$2.9 million) for violating the national law on protection of competition.

(AFX UK Focus) 2003-10-17 16:45  
GlaxoSmithKline, Boehringer Ingelheim face SAfrica fines over AIDS drugs sales

Previous | Next | All news for this company

Article layout: raw

JOHANNESBURG (AFX) - The South African units of GlaxoSmithKline PLC and Germany's Boehringer Ingelheim GmbH could face fines of up to 10 pct of their annual turnover after being found in breach of competition legislation in the sale of anti-AIDS drugs.

South Africa's Competition Commission has found the two pharmaceutical giants guilty of contravening the country's Competition Act and denying competitors access to an essential service in the sale of anti-AIDS drugs as well as charging excessively high prices.

"The firms have been found to have abused their dominant positions in their respective anti-retroviral markets," the Competition Commission said in a statement.

The Competition Commission found that the two firms had engaged in "excessive pricing", "an exclusionary act" and "denied a competitor access to an essential facility".

"Our investigation revealed that each of the firms has refused to license their patents to generic manufacturers in return for a reasonable royalty," commissioner Menzi Simelane said.

"We will recommend a penalty of 10 percent of the annual turnover of the respondents' anti-retrovirals in South Africa for each year that they are found to have violated the act," Simelane said.

fgb/srg/kdz/kl/jlw

# Etika v farmacevtski industriji ZAKONSKA PODLAGA



## Predpisi

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- Pravilnik o razvrščanju zdravil na liste, UL št. 110, 31.12.2010
- Pravilnik o oglaševanju zdravil, UL št. 105, 24.12.2010
- Pravilnik o določanju cen zdravil za uporabo v humani medicini, UL št. 102, 17.12.2010
- Pravilnik o natančnejših pogojih in postopku za ugotavljanje medsebojne zamenljivosti zdravil, UL št. 102, 17.12.2010
- Zakon o integriteti in preprečevanju korupcije, UL št. 45, 4.6.2010
- Zakon o medicinskih pripomočkih, UL št. 98, 4.12.2009
- Pravilnik o pogojih za opravljanje dejavnosti prometa z zdravili na debelo, UL št. 46, 19.6.2009
- Pravilnik o razvrščanju, predpisovanju in izdajanju zdravil, UL št. 86, 5.9.2008
- Zakon o zdravilih, UL št. 45, 9.5.2008

# Etika v farmacevtski industriji

## SAMOREGULACIJA - KODEKSI

### Kodeks obnašanja v odnosih med farmacevtsko industrijo in združenji bolnikov, junij 2008

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Sreda, 2. julij 2008

Farmacevtska industrija se zaveda, da ima številne skupne interese z organizacijami bolnikov, ki zastopajo in/ali podpirajo potrebe bolnikov in/ali njihovih skrbnikov. EFPIA je sprejela Kodeks obnašanja v odnosih med farmacevtsko industrijo in združenji bolnikov zato, da bi bili ti odnosi etični in pregledni.

[Več o tem](#)

### Kodeks obveščanja in seznanjanja o zdravilih na recept, junij 2008

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Petek, 22. april 2005

Forum spodbuja konkurenco med farmacevtskimi družbami. Namen Kodeksa Foruma vsekakor ni omejevanje lojalne konkurence. Nasprotno, namen Kodeksa je zagotavljanje zagotavljanje poštenih in verodostojnih promocijskih dejavnosti, izogibanje nepoštenim praksam in morebitnemu konfliktu interesov z zdravstvenimi delavci ter delovanje v skladu z veljavnimi zakoni in predpisi. Cilj Kodeksa je ustvariti okolje, v katerem splošna javnost lahko zaupa odločitvam o izbiri zdravila, saj so te sprejete na podlagi prednosti posameznega zdravila ter hkrati zdravstvenega stanja in potreb posameznega bolnika.

[Več o tem](#)



# Etika v farmacevtski industriji

- Je pomembna, saj je zaupanje bolnikov esencialno za razvoj in nenazadnje obstoj celotne panoge.