



**SANDOZ**



# **CEE Annual Compliance Update**

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**a Novartis company**

# Where is Central & Eastern Europe - ?



# CEE (24 countries)

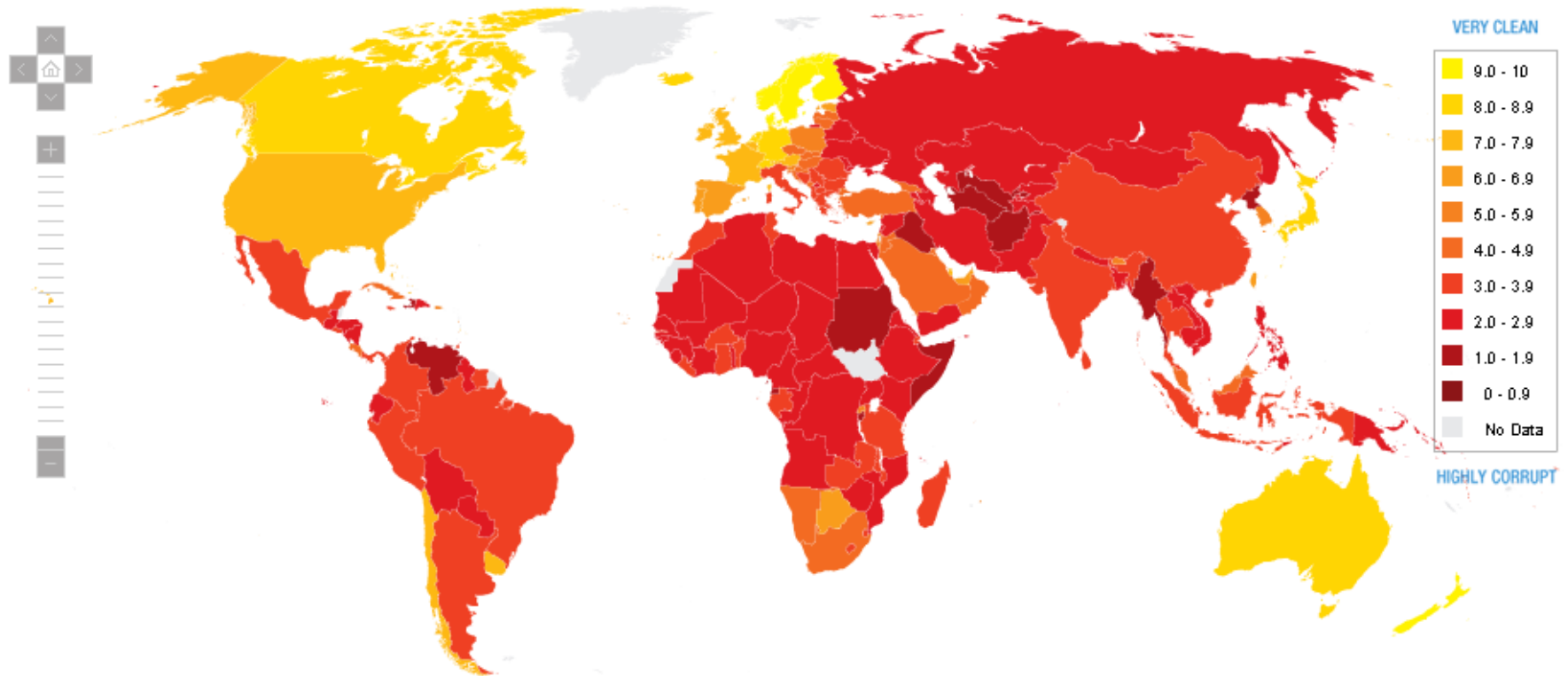
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- Armenia
- Bosnia-Herzegovina
- Bulgaria
- Czech Republic
- Croatia
- Estonia
- Greece
- Hungary
- Kirghizstan
- Latvia
- Lithuania
- Macedonia
- Moldova
- Mongolia
- Poland
- Romania
- Russia
- Serbia
- Slovakia
- Slovenia
- Tajikistan
- Turkey
- Turkmenistan
- Ukraine

# Compliance Environment

CORRUPTION PERCEPTIONS INDEX 2011

[VIEW COUNTRY RESULTS](#)



Source: Transparency International  
Link: <http://cpi.transparency.org/cpi2011/results/>

# Compliance Environment in CEE

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**EU Members**



**Candidates to EU**



**Non-EU Countries**

**Main reason: local legislation**

# Compliance Environment in CEE

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## EU Members

- Clear local legislation
- Strict enforcement
- Compliance culture (!)

## Candidates to EU

- Changing legislation – mandatory condition to join EU
- Changing culture



# Compliance Environment in CEE

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## Non - EU countries

- Vague legislation
- Non-compliant methods on the market
- The authorities have many other things to do
- Culture (!)

# Compliance Environment in CEE

**New Laws in CEE restricting promotional activities (introduced in last 12 months)**

▪ **Russia:**

- no gifts to HCPs, no samples
- limitations on interactions with HCPs (visits, trips)

▪ **Bulgaria:**

- requirements to sampling (tracking and archiving)

▪ **Ukraine:**

- HCPs are defined as public officials
- restrictions on OTC promotion





# Compliance Environment in CEE

**New Laws in CEE restricting promotional activities (introduced in last 12 months) TBC**



**▪ Slovakia:**

- promotional visits to HCPs are prohibited during patients' hours
- obligatory reporting of marketing expenses to the MoH, total amounts will be published on the MoH website
- HCP participation in the scientific events (congresses, seminars) has to be reported and will be published on web
- gifts to HCPs significantly restricted
- attendance of events (congresses, seminars) taxable for HCP as income
- non-interventional studies shall be approved by NHI per patient beforehand

# Compliance Environment in CEE

**New Laws in CEE restricting promotional activities (introduced in last 12 months) TBC**



- **Latvia & Lithuania:**

- restrictions to visit doctors during working hours - need to be pre-agreed

- **Serbia:**

- National Drug agency has introduced the control over the promotional materials

- **Poland:**

- new reimbursement law with changes related to the promotional activities in pharmacies

# Compliance Environment

Fines paid in CEE by other pharmaceutical companies (last 12 months)



- **Romania:**

- The Competition Council in Romania finalized a series of investigations carried out during 2008-2010, imposing fines of ~ 18 mill USD to several pharmaceutical companies and their distributors (anti-trust)

- **Turkey:**

- The competition authority fined 1 pharmaceutical company and its distributor 1% of the revenue in 2002.

# Compliance Environment

Fines paid in CEE by other pharmaceutical companies (last 12 months)

- **Ukraine:**
  - 125000 USD (anti-trust)
  - 6300 USD (promotional material)
- **Czech Republic:**
  - 2500 USD (bribery – medrep involved)



# Potential general recommendations

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- **More detailed and complete documentation about the activities is recommended: approvals, contracts, letters of confirmation, evidence of performance**
- **Common approaches to benchmarking should be developed by the industry associations in the countries**
- **Medical/Regulatory departments should be involved into promotional materials approval in order to avoid potential off-label promotion**
- **Awareness, especially in respect of applicable international legislation, must be ensured**

# Evergreen outside

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## Behaviour of unethical companies on local markets

- **Gifts**
- **Vouchers**
- **Trips**
- **Cash**



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We need generic companies in CEE at the same high compliance level!





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Thank you for your kind attention!

