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# Improving (risk) communication to prescriber and consumer

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# Position of regulators



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Benefit-risk communication to medicines users

How can regulators best meet the information needs of patients and healthcare professionals?

Workshop report

- › Regulators → healthcare professionals & consumers
  - making informed decisions
  - helping people make sense of risk (benefit-harm)
  - communicating safety information for achieving objectives of pharmacovigilance



# What are goals of communication?

- › Confer knowledge, experiences, give advise and recommendations, ask questions
- › Change
  - Knowledge
  - Attitudes
  - Behaviour





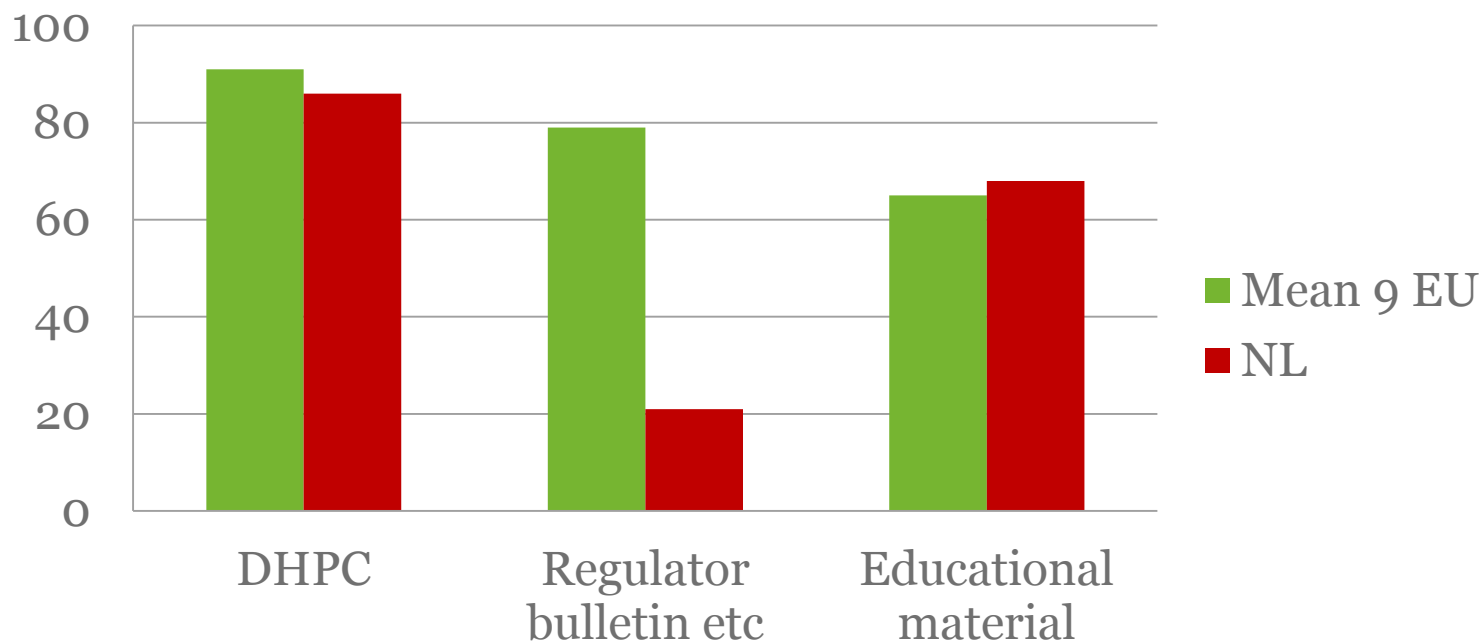
# Information from regulators in Europe

- › At time of authorisation:
  - European public assessment reports (EPAR)
  - Summary of product characteristics (SmPC)
  
- › Post-authorisation: updates on new indications, contra-indications, safety issues
  - Direct Healthcare Professional Communication (DHPC): hardcopy / email
  - Additional regulator communications: bulletin, newsletter, press release, website
  - Educational material for complex or particularly serious issues



# Prescribers – Scope survey: familiarity with safety communications

## Percentage of General Practitioners





# Effect of DHPC information on drug use

## More change:

- › Context: declining drug use prior to DHPC
- › Content: safety issues related to death/disability
- › Format: clear format, specific drug names/advise
- › Repetition: through multiple channels (email, pharmacist)

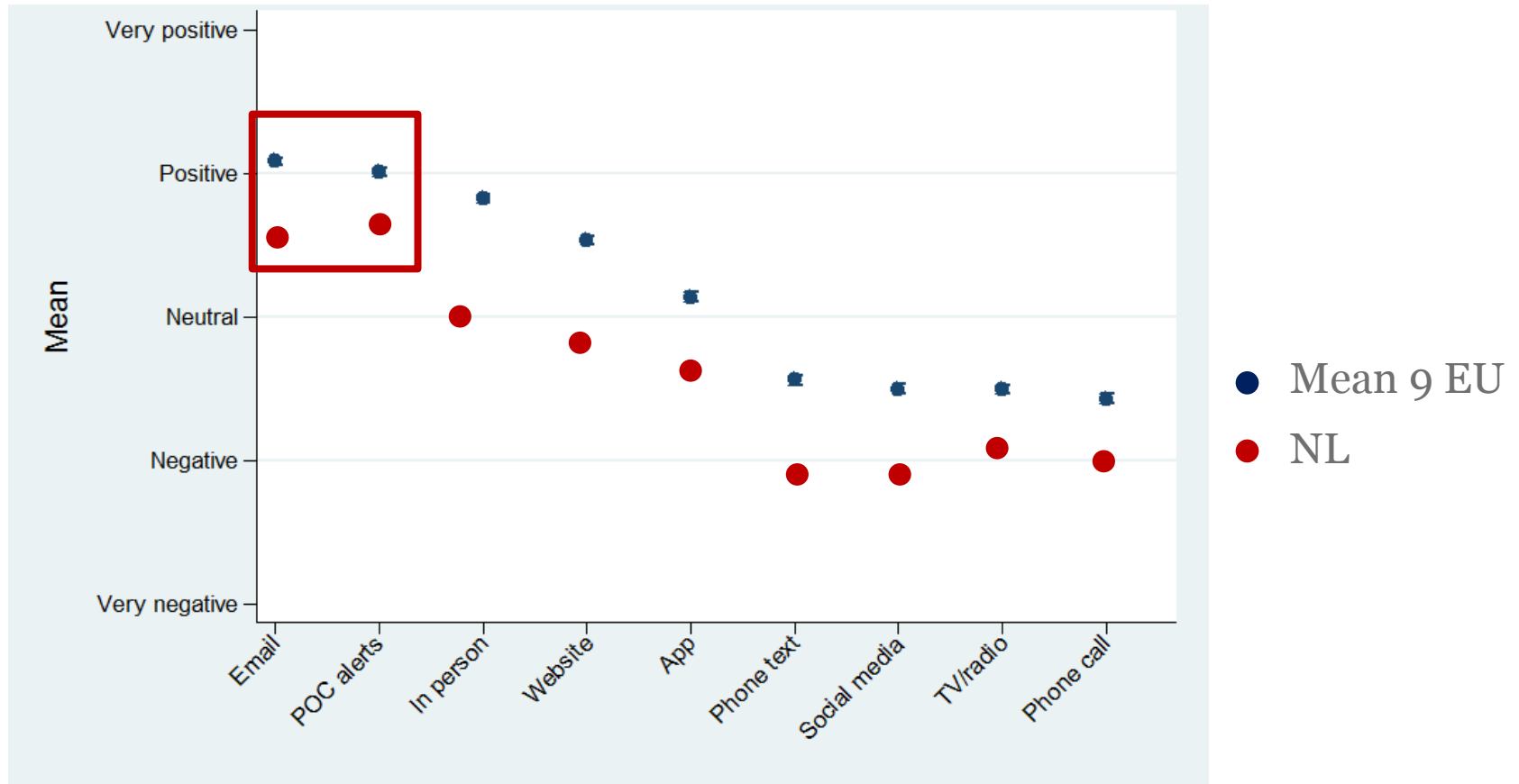
## Less change:

- › Drug: specialist drugs

But many DHPC do not require (immediate) action



# Alternative channels





# Senders and trust

- › I only read the safety information if I trust the sender

Most positively evaluated senders: *professional bodies, regulator*

Intermediately evaluated senders: *researchers, colleagues*

Most negatively evaluated senders: *pharmaceutical industry, press*





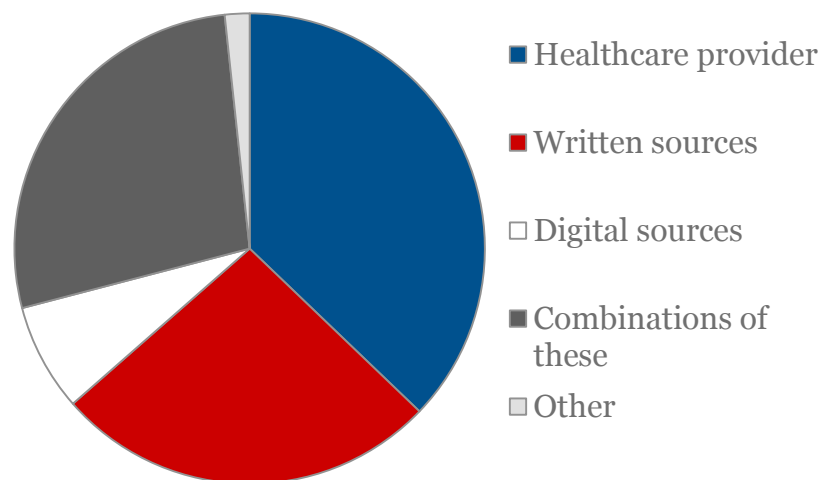
## Patients - NIVEL survey

- › 6 out 10 seek information about medicines
  - when starting new medication (45%)
  - when using medication (21%)
  
- › Benefits and risks
  - decision whether to start / what it is for
  - fear for / experiencing side effects
  - experiences from others



# Sources used when seeking information

- › Patient information leaflet (89%)
- › General practitioner (69%)
- › Internet (66%)
- › Pharmacist (59%)
- › Specialist (32%)
- › ..
- › ..
- › Apps (3-6%)





# Information about benefits in leaflets

|  | Generic (25) | Branded (25) | Black Triangle (50) |
|--|--------------|--------------|---------------------|
| What it is for                           | 100%         | 100%         | 100%                |
| Rationale for taking                     | 20%          | 32%          | 64%                 |
| What if you don't take                   | 28%          | 20%          | 20%                 |
| Duration of treatment                    | 32%          | 48%          | 66%                 |
| Uncertainty benefits                     | 40%          | 40%          | 34%                 |
| Proportion of patients likely to benefit | 0%           | 0%           | 0%                  |



# Important for patients

- › Trust in source
- › Clear information
- › Up-to-date information
- › Applicability for own situation



# Finding up-to-date information

- › Finding the right source
  - advise from healthcare providers
  - [www.geneesmiddeleninformatiebank.nl](http://www.geneesmiddeleninformatiebank.nl) is not known
- › Finding the right information within a source
  - structure/lay-out/navigation
  - complexity/amount



# Communication about generics

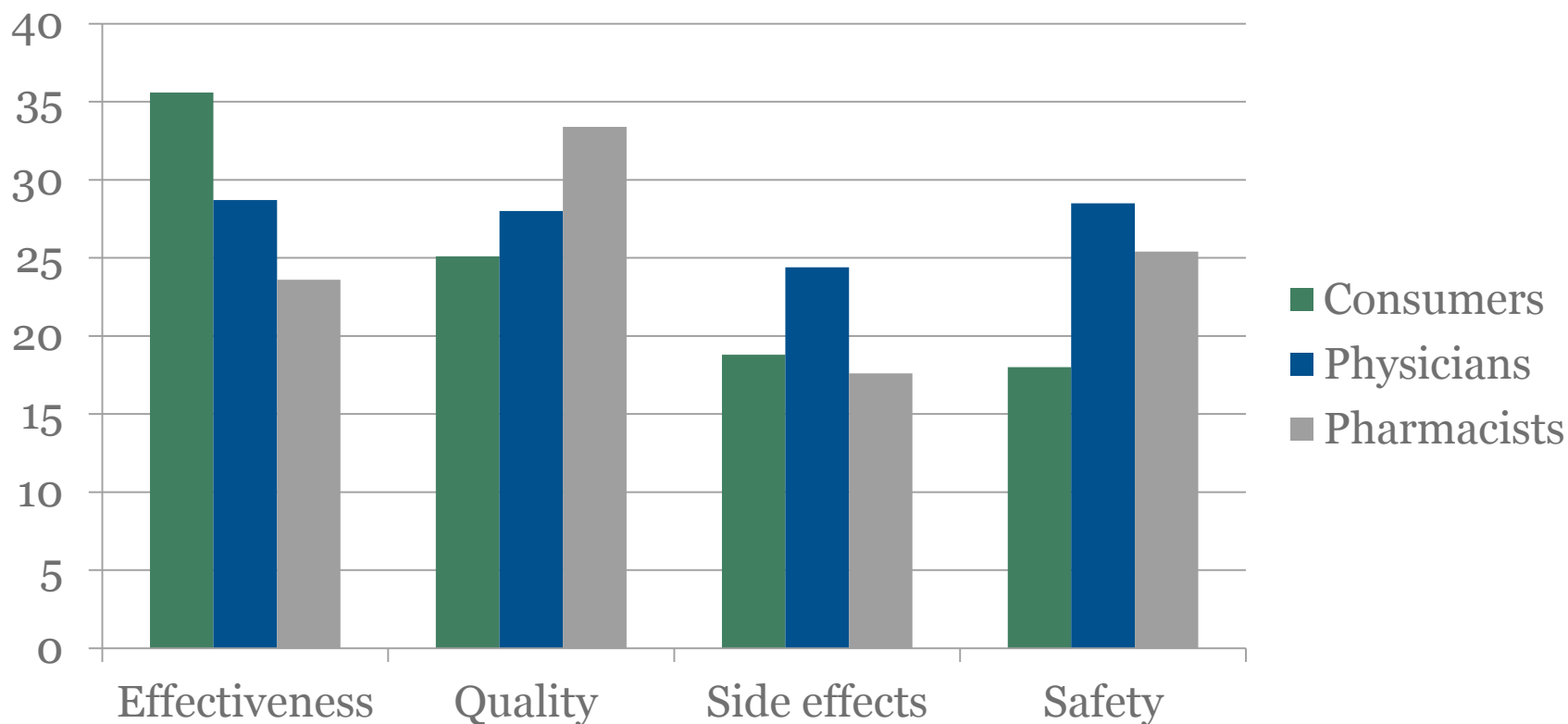
- › Confer knowledge, experiences, give advise and recommendations, ask questions





# Negative perceptions generics – review

% with negative perceptions





# Perceptions of generics

| Physicians                                  | Patients  | Pharmacist                                |
|---|---|---|
| Lack of confidence in foreign manufacturers | Lack of confidence in generics                  | Concerns regarding patients understanding |
| Doubts about equivalence                    | Negative / positive experiences                 | Concerns about correct taking behaviour   |
| General preference for branded medication   | Concerns about change in appearance/package     |   |
| Preference for brands in specific cases     | Difficulties with adherence                     |   |
| Low cost main reason to prescribe generic   | Lack of involvement in decision                 |   |
|   | Preference for brands for more serious diseases |   |





# Gaps in risk communication knowledge





# Acknowledgement

- › **Scope Work Package 6 – Risk Communications**
  - Peter Mol, Sieta de Vries, e.a. **HCPs’ perspectives on safety communication about medicines**