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**Results of a literature research and
public-opinion poll about herbal
medicinal falsifications and the
subsequent regulatory
recommendations**

Iris Müller

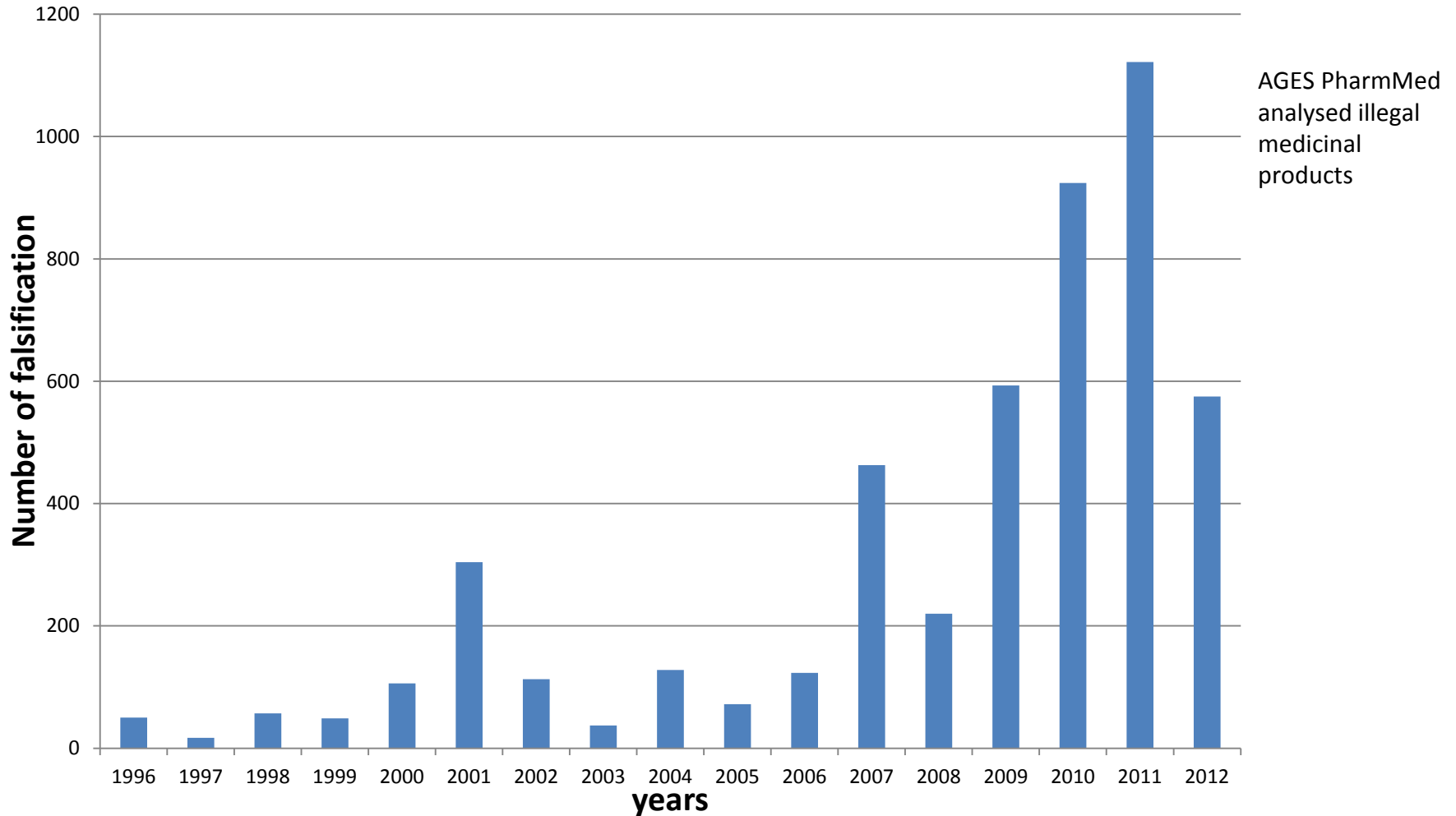


Topic

- 1) Falsification of medicinal product a statistical overview
- 2) Examples for falsified herbal products
- 3) Problems of falsified herbal products
- 4) Questionnaire for patients
- 5) Activities for fighting against falsifications
- 6) Relevance of the activities for herbal medicinal products
- 7) Recommendations for the fight against falsified herbal products



Falsification of medicinal drugs



Examples of falsified herbal drugs

Product	Productstatus	Claim	Ingredients
Power tabs	Food Additives	Pur Herbal (Erection)	Sulfoaidenafil
Staminex	Food Additives	Pur Herbal (Erection)	Hydroxyhomosildenafil
Virilex Man	Food Additives	Pur Herbal (Erection)	Sulfohydroxyhomosildenafil
Meizitang	Food	Pur Herbal (Weightreduction)	Sibutramin Phenolphthalein
Fortodol	Food Additives	Pur Herbal (Pain)	Nimsulide
Paiyouji	Herbal	Pur Herbal (Weightreduction)	Phenolphthalein Sibutramin
Powertabs	Food Additives	Pur Herbal (Erection)	Thiodimethylsildenafil Butyltadalafil
Rize 2 the Occasion	Food Additives	Pur Herbal (Erection)	Thiodimethylsildenafil
Cardiotium	Herbal	Pur Herbal (Heart Disease)	Losartan Atorvastan
Instant Slim	Herbal	Pur Herbal (Weightreduction)	Sibutramin
Sport Burner	Herbal	Pur Herbal (Weightreduction)	Sibutramin
Zhong Hua Niu Bian	Herbal	Pur Herbal (Erection)	Glibenclamid
Power tabs iErect	Food Additives	Pur Herbal (Erection)	Thioaidenafil Dithodesmethyl-carbodenafil
Start up fo him	Food Additives	Pur Herbal (Erection)	Tadanafil



Falsified herbal products

Problems:

- There are some herbal medicinal product in the literature
- But the most falsified herbal products are food or food supplement (99%)
- The supply chain for falsified herbal products is the internet



Questionnaire for falsified herbal products

- Questionnaire for pharmaceutical industry
 - Have there exist counterfeit drugs?
 - Which product was falsified? (drug substance, type of falsification)
 - Which supply chain was used for the falsified drug?
 - Which type of protection systems did they use?
 - Which supply chain is generally used?
 - Do you recommend herbal food supplement with health claims?



Questionnaire for falsified herbal products

- Questionnaire for patients:
 - Do you buy herbal products?
 - Why do you buy herbal products?
 - Where do you buy herbal products?
 - Which inspiration do you have for buying herbal products?
 - What is legally a food supplement?
 - Which are the differences between medicinal product and food supplement?
 - What is a counterfeit drug?
 - Where are the most counterfeit drugs placed in?



Analysis of the questionnaires

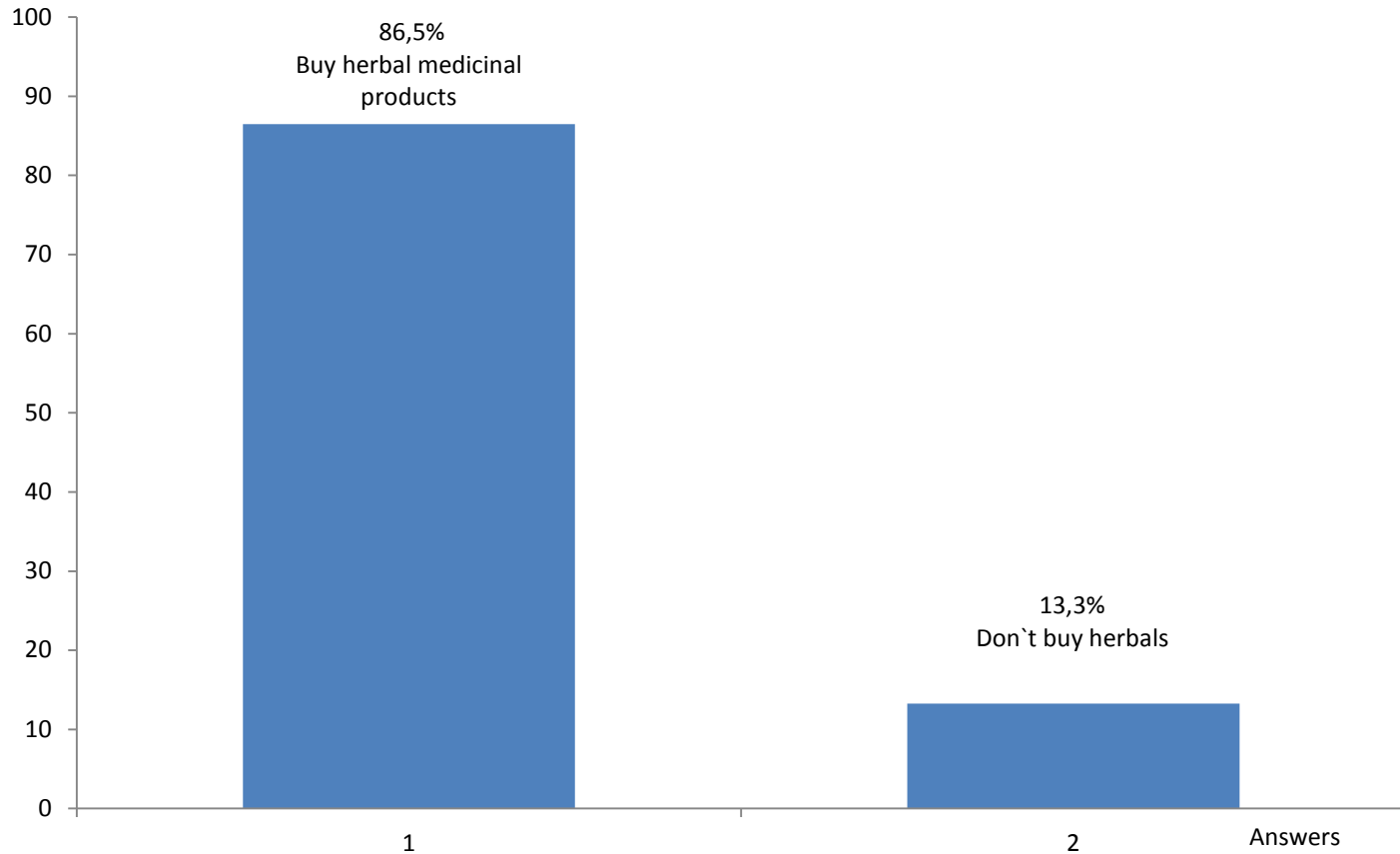
Unfortunately only four pharmaceutical industries answered the questionnaire.

=> There are no results

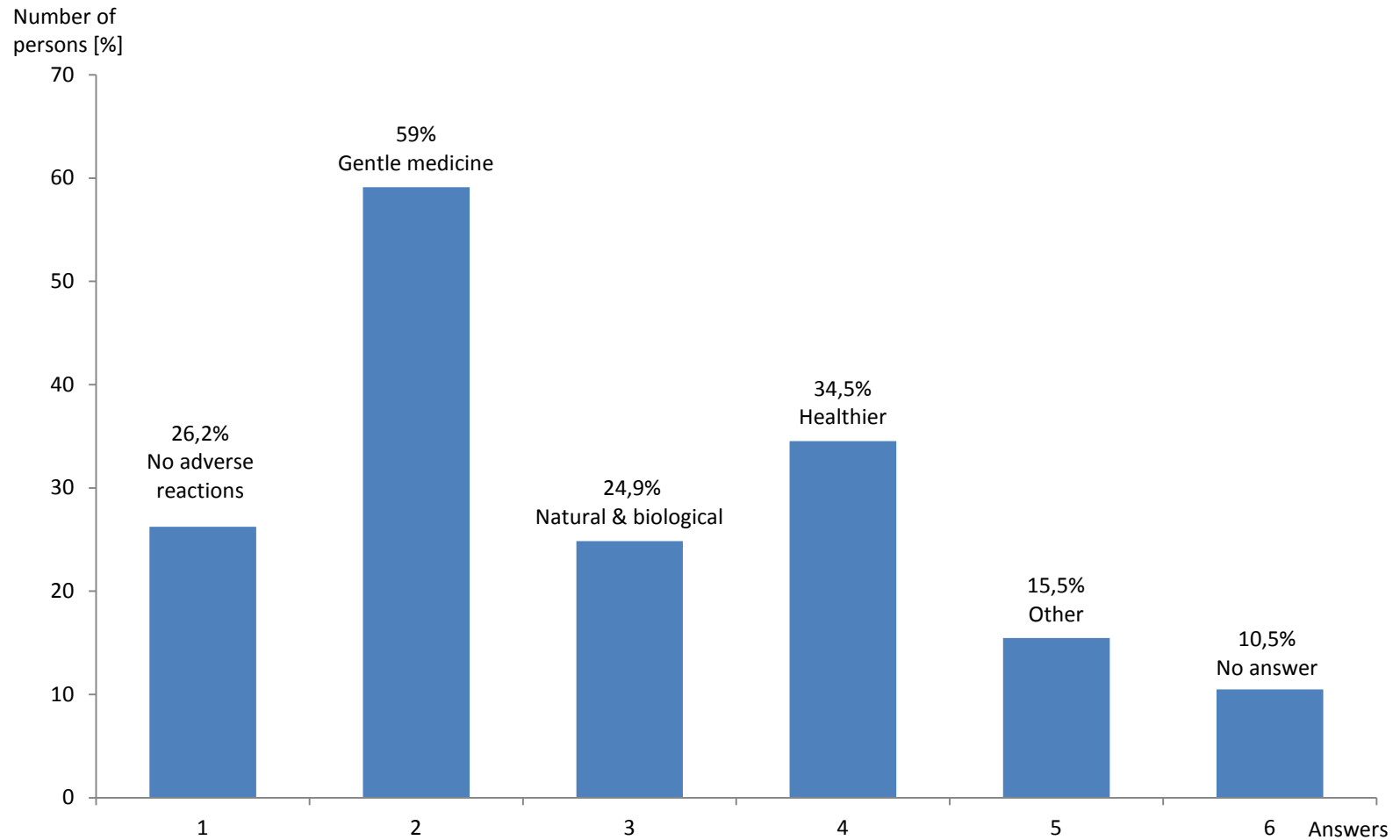


How many persons buy herbal products?

Number of persons [%]

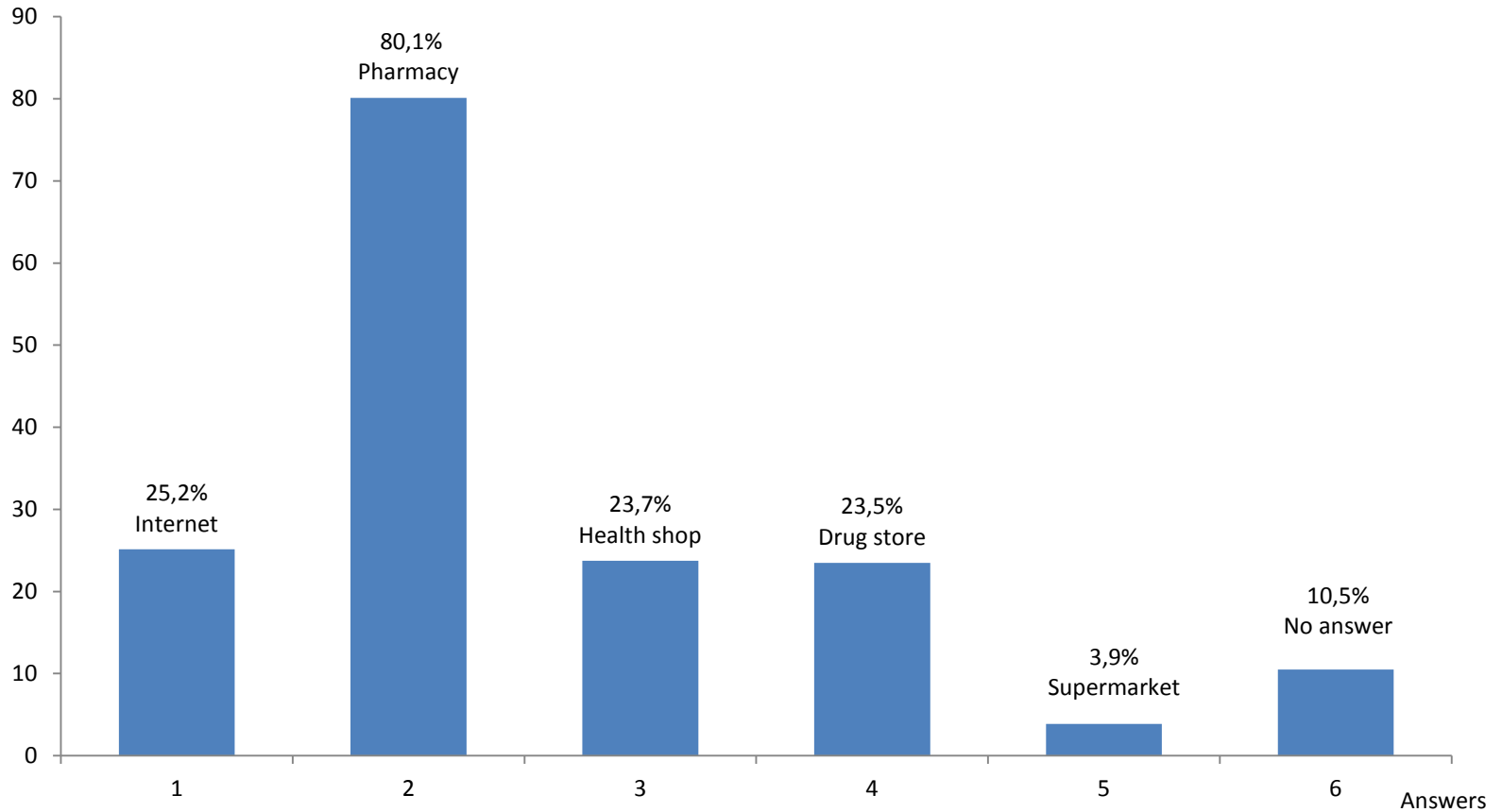


Why do you buy herbal products?



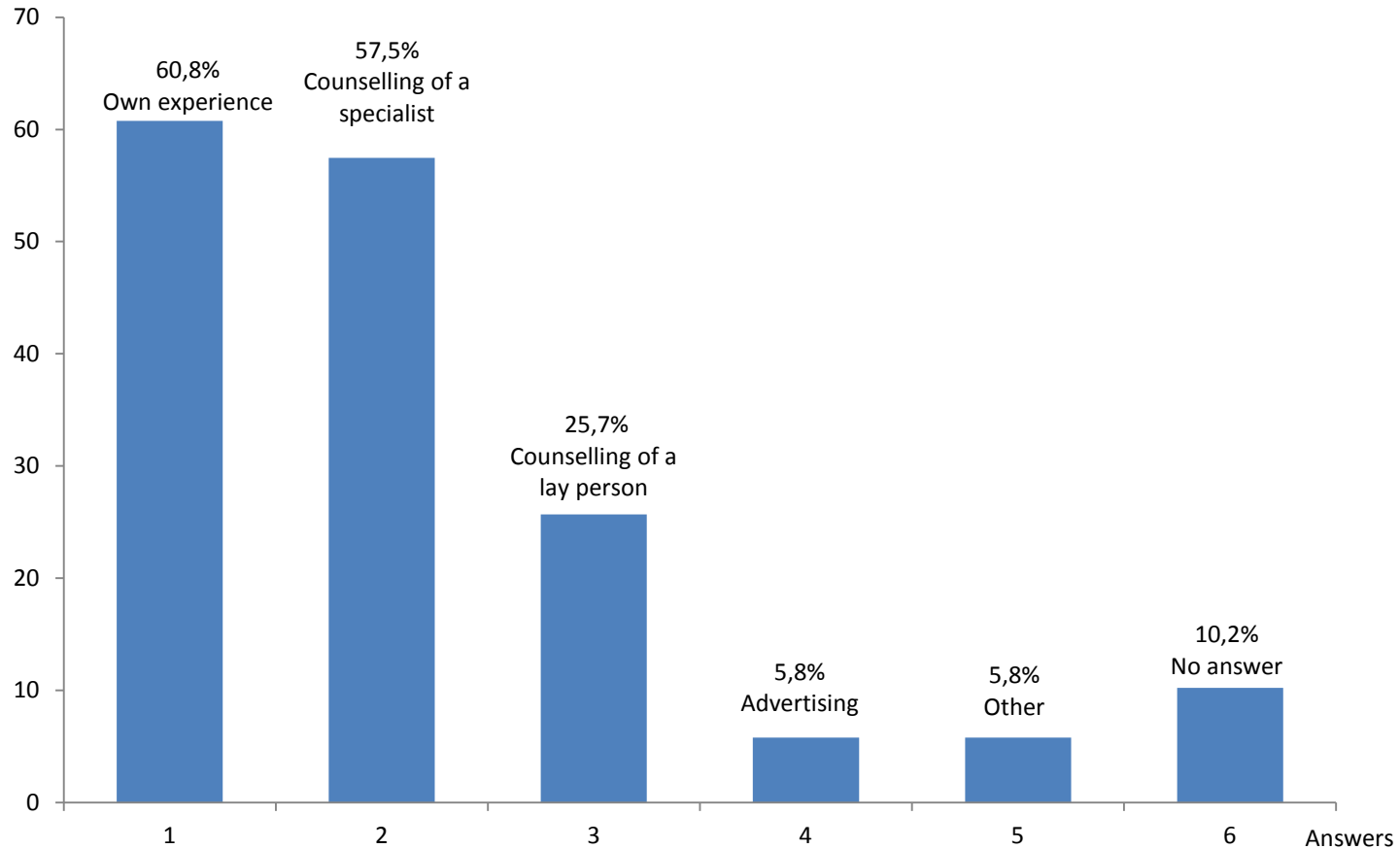
Where do you buy herbal products?

Number of persons [%]



Do to which inspiration do you buy herbal products?

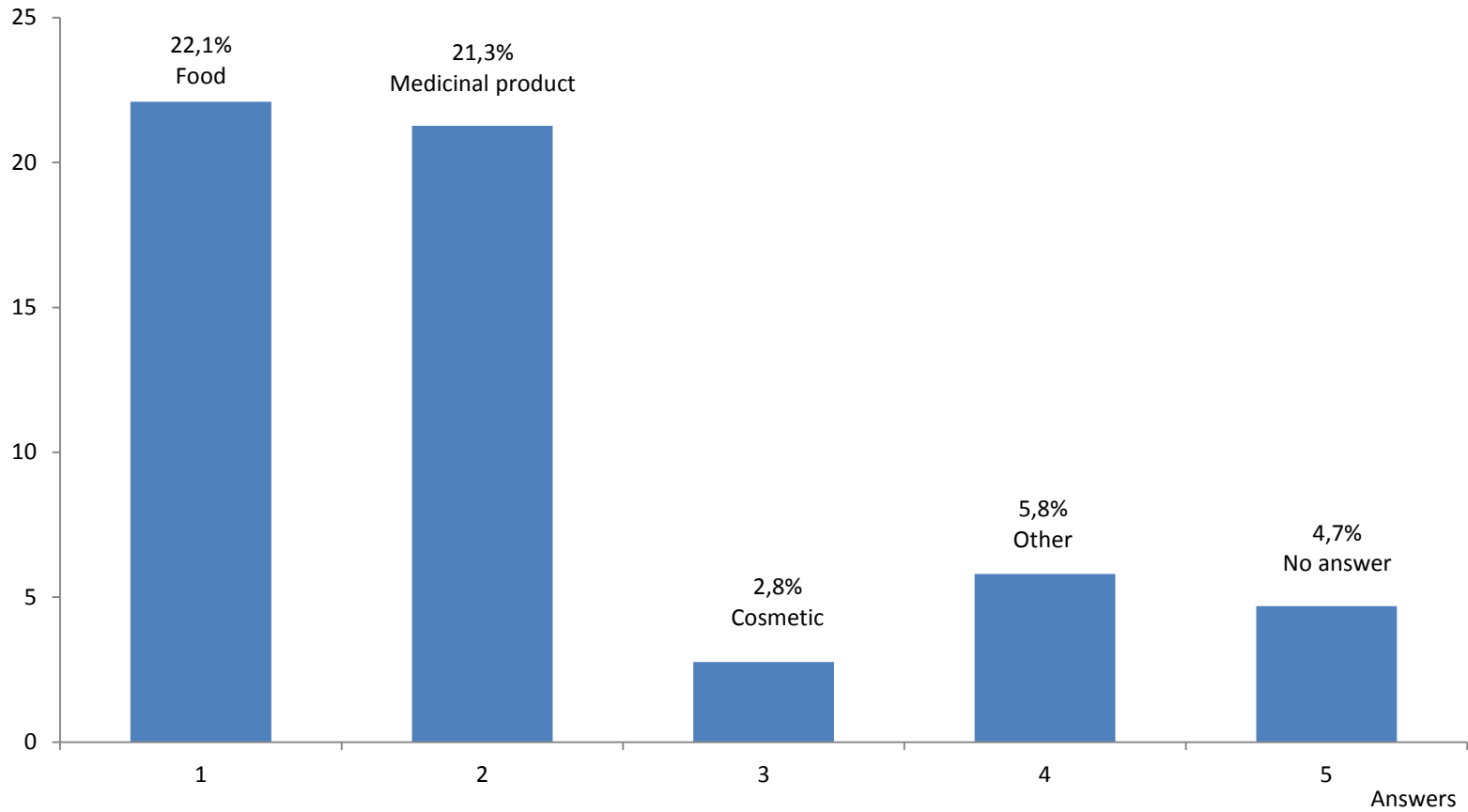
Number of persons [%]





What is a food supplement from the legal site?

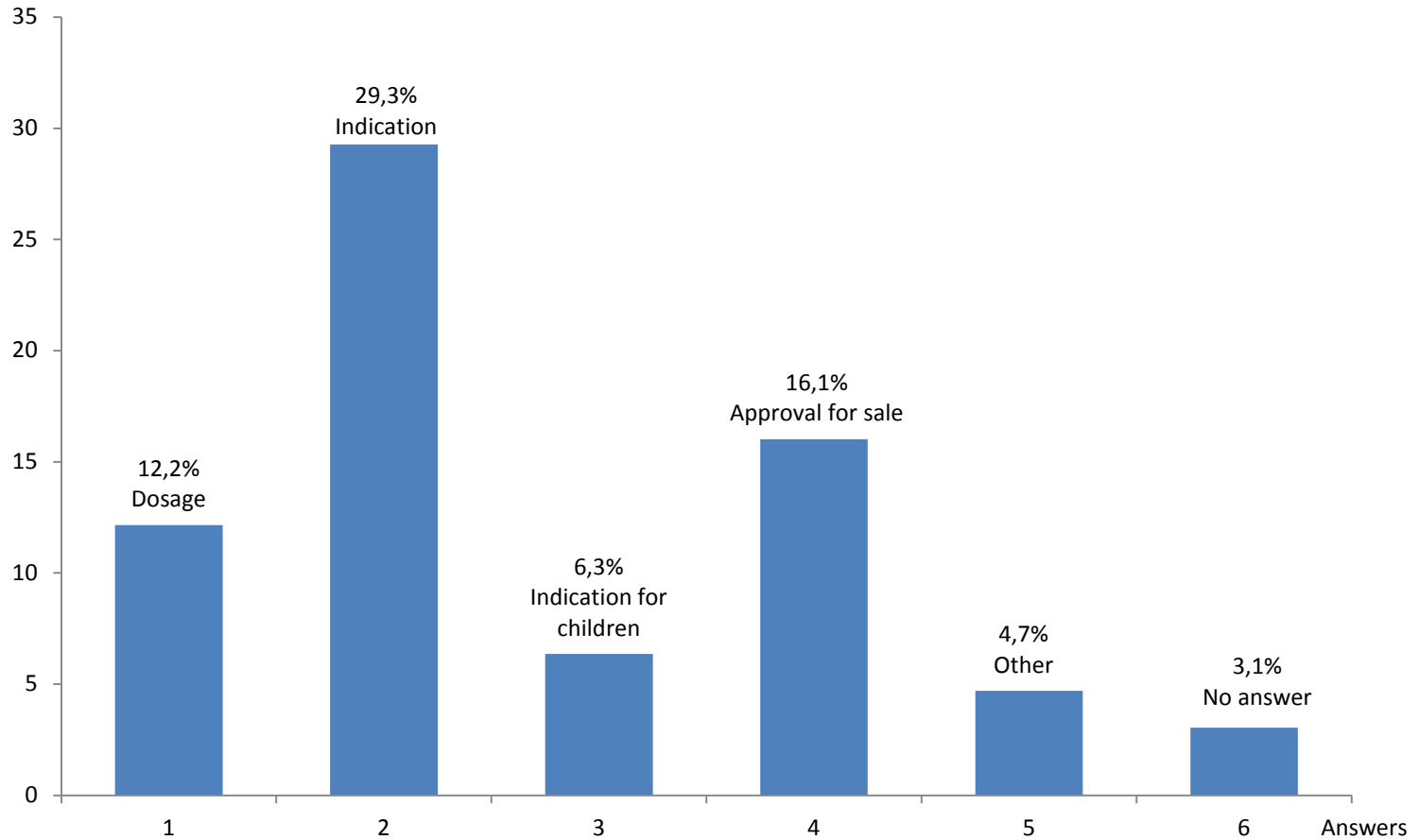
Number of persons [%]



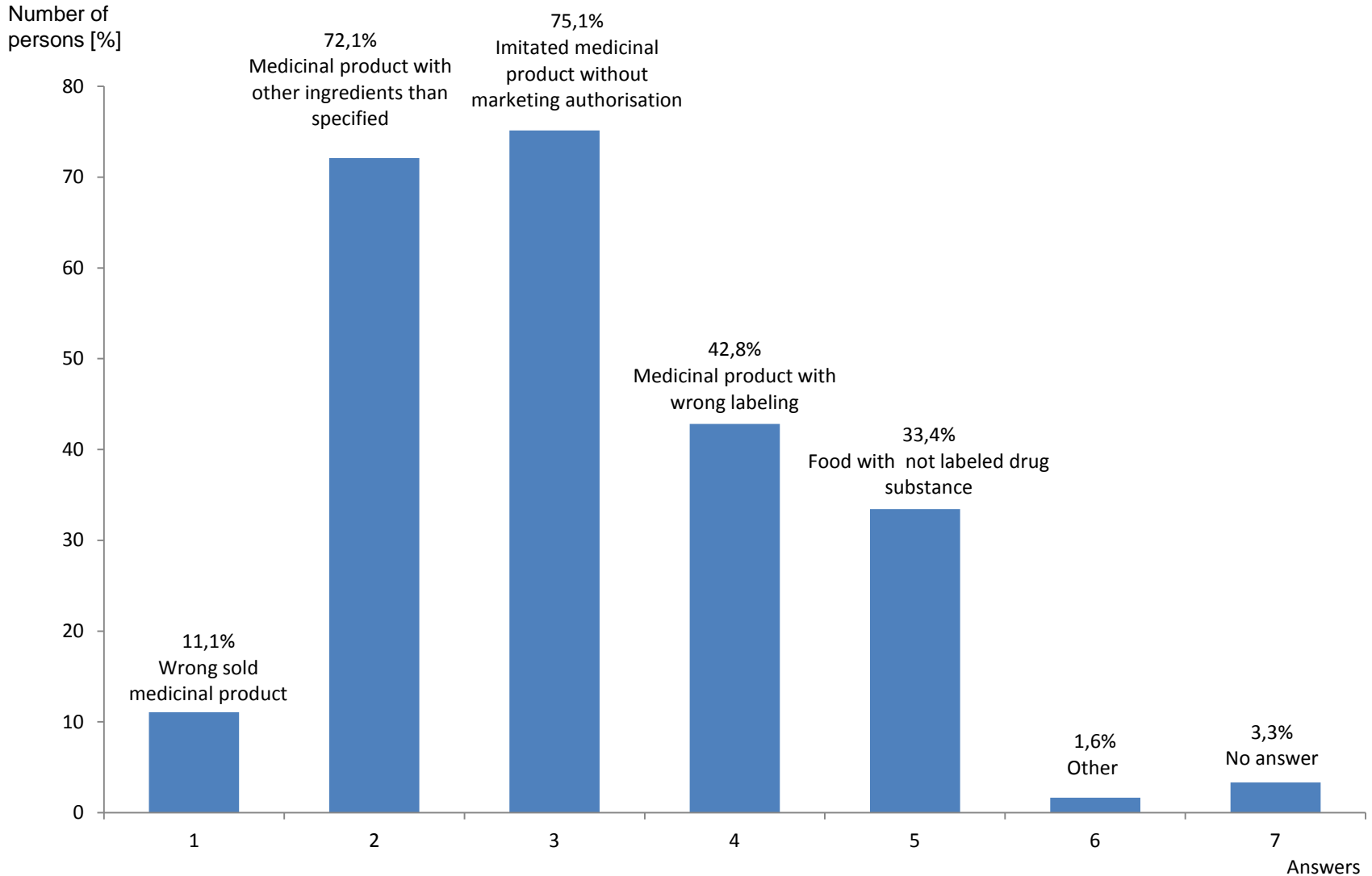


What is a falsified herbal product?

Number of persons [%]



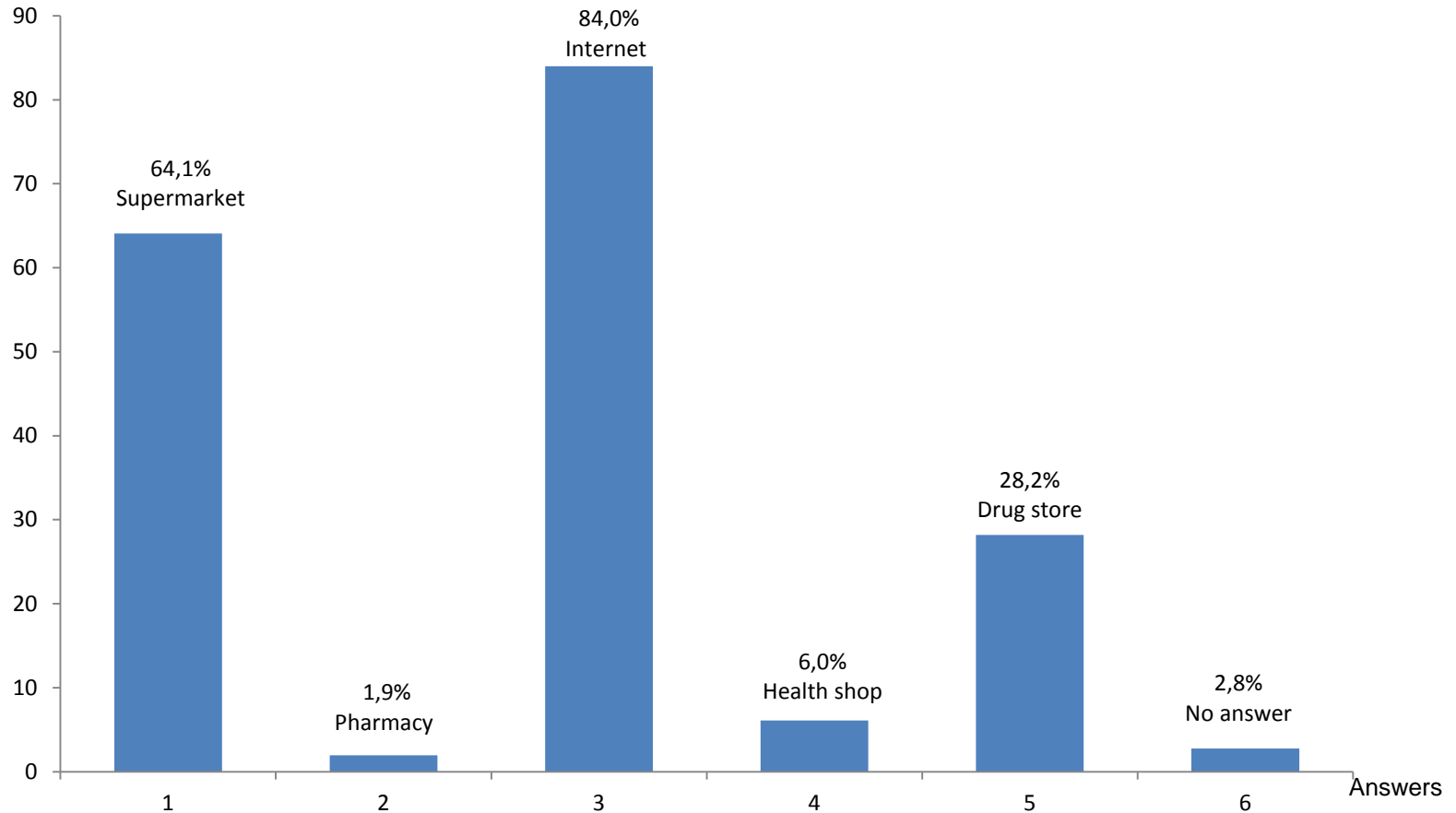
What is a falsification in your opinion?





Which is the best place for sale of counterfeit drugs?

Number of persons [%]





Conclusion of the questionnaires for patients

- 80% buy herbal products
- 80% buy the herbal product in the pharmacy; only 25% via internet
- 59% buy herbal products because of gentler medicines
- 25% because of natural and biological origin
- 35% because of healthier medicines
- The most peoples buy herbal products because of a specialist counselling or their own experience



Conclusion of the questionnaires for patients

- About 20% think food supplements are from the legal site food; other 20% think it`s a medicinal product.
- 72 - 75% think a falsified product is a imitated medicinal product without marketing authorisation or a medicinal product with wrong ingredients
- Only 33% think that food supplements with not labelled medicinal drug substances are falsified although
- 84% think that the internet is the best place for sale of falsification and counterfeits



General activities for fighting against falsification

- Governmental activities
 - Founding of an Anticounterfeiting Taskforce

- Regulatory activities
 - Falsification Guideline (2011/62/EC)
 - Safety signature (Data matrix code)
 - Originality protection
 - New recommendation for GMP for active substances and excipients
 - New recommendation for internet selling

- Technical activities
 - Data matrix code
 - Test procedures for identifying falsifications



Relevance of these activities for fighting against falsification for herbal products

- Political activities are only relevant for herbal medicinal products not for food supplements or cosmetic
- Regulatory activities are partially relevant for herbal medicinal products, because of the different prescription/distribution status.
- Technical activities are relevant for herbal medicinal products and for food supplements.



Recommendation for the fight against herbal counterfeit drugs

- All herbal products for healthier life should have the state of a approved medicinal product
- Foundation of a new group of medicinal product (herbal healthy products)
- Herbal healthy products include herbal medicinal products, food supplement, functional food, dietetic food with health claims and cosmetic with prophylactic propose.



New Group of herbal healthy products, with a registrations procedure for approval by authority



Recommendation for the fight against herbal counterfeit drugs

- Data matrix code should be necessary for medicinal products with prescription
- Herbal healthy products with an indication of weight reduction or erectile dysfunction should be listed on the black list.



Each product , where exists a risk for falsification can be tracked back

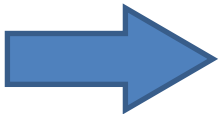


Recommendation for the fight against herbal counterfeit drugs

- No sale of these herbal healthy products outside the pharmacy
- Only sale in internet-pharmacies which are local pharmacy



A medical advice is possible in this way



No sale of medicinal products via normal internet



Thanks for your
attention