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**Counterfeits and imitations of Viagra[®] and
Cialis[®] tablets: trends and risks to public
health**

A survey of the analyses carried out at the Dutch
National Institute for Public Health and the
Environment in the time period 2000 - 2004

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Abstract

Counterfeits and imitations of Viagra[®] and Cialis[®] tablets: trends and risks to public health - A survey of the analyses carried out at the Dutch National Institute for Public Health and the Environment in the time period 2000 - 2004.

During the last years de Dutch market has been flooded with falsifications of Viagra[®] and Cialis[®]. Both products are used for the treatment of erectile dysfunction. This report is about the trend analysis of these falsifications during the years 2000 – 2004. The risks of these products to public health are surveyed and also described.

The following conclusions are drawn:

- a) There is a trend towards products containing other active compounds than sildenafil and tadalafil, the compounds of Viagra[®] and Cialis[®].
- b) There is a trend towards the addition of (unknown) active compounds to herbal products.
- c) Falsifications are a risk to public health: they are produced without adequate quality control; they mislead the users concerning manufacturer and composition.
- d) The risk to public health is much higher if unknown, chemical compounds are added to herbal products. The effects and side effects of these compounds are unknown. Besides, herbal products are often considered to be natural and therefore harmless.
- e) In order to detect trends and new risks in the future, an ongoing survey of the legal and illegal market by analysing samples is needed.

The trend analysis and risk survey are based on the analytical results of about 400 samples. These samples were sent in by governmental inspectorates for chemical analysis. The samples give an insight into the developments of the illegal market. However, they may not be representative for the market supply.

Keywords: Viagra, Cialis, imitations, trend analysis, counterfeited medicines.

Het rapport in het kort

Nep en namaak Viagra® en Cialis® tabletten: trends en risico's voor de volksgezondheid - Een overzicht van de analyses uitgevoerd bij het Rijksinstituut voor Volksgezondheid en Milieu in de periode 2000 - 2004.

De Nederlandse markt is de afgelopen jaren overspoeld met vervalsingen van Viagra® en Cialis®. Beide producten worden gebruikt voor de behandeling van erectiestoornissen. Dit rapport gaat over een trendanalyse van deze vervalsingen over de jaren 2000 – 2004. Ook de risico's van deze producten voor de volksgezondheid zijn geïnventariseerd en beschreven.

De volgende conclusies zijn getrokken:

- a) Er is een trend naar producten, die andere actieve verbindingen bevatten dan sildenafil en tadalafil (de verbindingen, die in Viagra® en Cialis® zitten).
- b) Er is een trend naar het toevoegen van (onbekende) actieve verbindingen aan kruidenproducten.
- c) Vervalsingen zijn een risico voor de volksgezondheid: ze worden geproduceerd zonder adequate kwaliteitscontrole; ze misleiden de gebruiker wat betreft de fabrikant en de samenstelling.
- d) Het risico voor de volksgezondheid is veel groter als er onbekende, chemische verbindingen aan kruidenproducten worden toegevoegd. Van deze verbindingen zijn de werking en bijwerking niet bekend. Bovendien worden kruidenproducten vaak gezien als natuurlijk en dus ongevaarlijk.
- e) Om in de toekomst trends en nieuwe risico's te kunnen vaststellen moeten de legale en illegale markt voortdurend gevolgd worden door monsters te analyseren.

De trendanalyse en de risico-inventarisatie zijn gebaseerd op de analyseresultaten van circa 400 monsters. Deze monsters zijn door de overheidsinspecties ingezonden voor chemische analyse. De monsters geven inzicht in de ontwikkelingen van de illegale markt, maar zijn daar mogelijk geen representatieve afspiegeling van.

Trefwoorden: Viagra, Cialis, imitaties, trendanalyse, geneesmiddelenvervalsingen.

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Summary

After the introduction of Viagra[®] and Cialis[®] in 1998 and 2002, respectively, the Dutch market has been flooded with falsifications of these medicines. In the time period 2000 - 2004 about 400 samples of Viagra[®], Cialis[®], their counterfeits, and their imitations were analysed at the Dutch Institute for Public Health and the Environment (RIVM). The analyses were carried out on behalf of the Dutch Health Care Inspectorate (IGZ) and the Food and Consumer Product Safety Authority (VWA). In this report a trend analysis of these falsifications is described and the risks to public health in relation to the different types of products are discussed. Although the trend and risk analyses are limited to the samples received, several trends are observed and conclusions are drawn.

The samples were analysed for the presence of sildenafil, the active ingredient of Viagra[®], and tadalafil, the active ingredient of Cialis[®]. If other pharmacologically active substances were identified, this was also reported. In addition the samples were analysed for the similarity with genuine Viagra[®], Cialis[®], or formerly analysed samples.

For Viagra falsifications, the samples varied from genuine Viagra[®], obtained under suspicious circumstances, via look-alikes (counterfeits) to products claiming or suggesting a similar effect, but which could be distinguished from the genuine Viagra[®] by simple visual inspection (imitations).

Look-alikes were analysed containing: a) sildenafil in the right amount; b) sildenafil in a much lower amount; c) other active pharmaceutical ingredients.

Imitations were analysed containing: a) sildenafil; b) sildenafil in combination with another active ingredient; c) no sildenafil, but another active ingredient; d) no active substance. In most cases the identified compounds were not declared on the label package. In herbal products we identified new sildenafil analogues, of which information about action and side effects is not available.

During the time period covered by this report three Cialis imitations were found; good looking Cialis counterfeits were found in the official supply chain on several places over the world. Analyses revealed that some batches contained tadalafil, other batches tadalafil in combination with sildenafil.

These illegal medicines represent a serious risk to public health: a) the production of the substances and the manufacturing of the products is neither regulated nor supervised by European authorities; b) the information on the package about the composition of the products is often incorrect or incomplete; c) the presence of other pharmaceutically active ingredients than the one declared or suggested can lead to unexpected and undesired effects; d) especially the herbal products with pharmacologically active substances cause extra risks, because consumers tend to believe that herbal products are harmless, and therefore will not attribute the effects to the products.

In order to follow the trends on the illegal market and to prevent illegal products to enter the official supply chain a more structured approach for sampling of the products available on the market is required. It will still be necessary to analyse samples, while otherwise new analogues will not be discovered. Analytical results can also be used to trace connections between samples, traders, and production sites.

1. Introduction

In September 1998 a European marketing authorisation (MA) was granted to the company Pfizer for the product Viagra[®], containing the active pharmaceutical ingredient (API) sildenafil. Its therapeutic indication is the treatment of erectile dysfunction [1]. Since its introduction Viagra[®] is falsified numerous times. From the beginning of 2000 a large number of samples was tested at the RIVM, within the Centre for Quality of Chemical-Pharmaceutical Products (RIVM-KCF) in cooperation with the Laboratory of Analytical Chemistry (RIVM-LAC).

The introduction of Viagra[®] was followed by Cialis[®] from the company Lilly in November 2002 and by Levitra[®] from the company Bayer in March 2003 [1]. Both products have a similar therapeutic indication as Viagra[®]. The APIs in Cialis[®] and Levitra[®] are tadalafil and vardenafil, respectively. As it was expected that falsifications of Cialis[®] and Levitra[®] would follow shortly, our analytical methods were adjusted for qualitative and quantitative analysis of vardenafil and tadalafil as well.

All individual samples were sent in to verify the presence of sildenafil or related substances, or to establish the similarity with the genuine product or formerly analysed samples. A variety of samples was sent in: Viagra look-alikes with or without sildenafil, with or without other APIs; tablets with different colours and shapes than Viagra[®], but with sildenafil; all kinds of dosage forms; herbal products with sildenafil; products with packages and information leaflets; products without any information. Even herbal products with new compounds, which are structurally related to sildenafil, but of which no toxicological data are available, were identified. At the end of 2004 Cialis[®] falsifications were sent in for analysis.

Due to the variation in the types and the increase in the number of samples other questions became important: is this a risk to the public health and is there a trend in the type of falsifications? As the falsifications were not only look-alikes, but also products with a different appearance, but a similar claim, falsifications were divided into counterfeits and imitations. Counterfeits are defined as products having a similar appearance compared to the original product. Imitations are defined as products that do not look like the original product, but claim or suggest a similar pharmacological effect.

In this report a trend analysis is described and the risks to human health of these products are discussed, based on the analytical results from the beginning of the project in 2000 to the end of December 2004.

2. Materials and methods

2.1 Materials

Reference samples, i.d. genuine products, were obtained from pharmaceutical wholesalers in the Netherlands or directly from the MA holders. Reference standards were obtained from chemical suppliers or the MA holders.

Most samples were analysed within the project: “Control of Human Medicines”, subproject “Pharmaceutical Crime” on behalf of the Dutch Health Care Inspectorate (IGZ), and the project: “Herbs, Food, and Medicines” of the Food and Consumer Product Safety Authority (VWA). Some samples were received directly from other governmental bodies (Customs, Police). In most cases the exact origin of the samples was only known to the inspectors and unknown to the authors and the technicians that performed the analysis. Most samples were confiscated by the governmental bodies and some samples were obtained via the internet. Samples were sent in different packages: in blisters, with information leaflet and box; just in a blister; only in an unlabeled plastic bag; in a plastic container with seal, with an opened seal, or without seal. Sometimes additional information was obtained from the inspector, such as: “known in the scene as herbal Viagra”, or: “aphrodisiac with a strong effect”. The dosage forms of the products also varied: tablets, gels, capsules, powders for filling capsules, and beverages.

The samples were analysed to determine whether the products contained sildenafil or other APIs, or to determine the similarity with the genuine product or formerly analysed samples.

2.2 Analytical methods

For qualitative and quantitative analysis several techniques were used over time due to the increasing demand to be able to detect, identify, and quantify other APIs or structurally related substances that might be present in the samples. The first samples were analysed by a combination of thin layer chromatography and UV/Vis-spectroscopy. Later on high pressure liquid chromatography with diode array detection (HPLC-DAD) was applied, whereas the latest samples were analysed by HPLC-DAD with on-line tandem mass spectrometry.

For determination of the similarity of samples with the genuine products or with previously analysed samples Near Infrared (NIR) spectroscopy was applied [2,3]. Spectra of a sample were compared to the spectra in a library and mean correlation coefficients were calculated. Three libraries were used to screen the unknown tablets:

- a) A reference Viagra[®] library was constructed at the beginning of the project consisting of 70 spectra obtained from seven batches of 50 mg reference Viagra[®] samples. The reference Viagra[®] library is validated regularly by analysing new batches of reference Viagra[®] samples. The spectra obtained are then added to the library, which resulted in a total of 117 spectra at the end of 2004.
- b) The second library contained spectra of all measured samples and was used to check if a new sample had been analysed previously. This library expands continuously.
- c) At the end of 2004 a small reference Cialis[®] library was constructed consisting of 34 spectra obtained from reference Cialis[®] samples: three batches of 20 mg, one batch of 10 mg, and one single tablet of an additional batch of 20 mg Cialis[®].

Not for all samples qualitative, quantitative, and NIR analyses were carried out; this depended on the request of the inspector, who sent in the sample for analysis.

2.3 Trend analysis

A trend analysis was carried out by dividing the samples into categories, based on the appearance of the dosage form and the analytical results (Tables 1 and 2, page 9).

The result of the analysis is visualised by creating graphs of the numbers of samples per year and per category as is shown in the Figures 1 - 11.

The samples were divided into the five main categories *Genuine*, *Counterfeit*, *Imitation*, *Analogue*, and *Others*. *Genuine* tablets could not be distinguished from the original medicine. *Counterfeit* tablets are defined as falsifications that are look-alikes of the genuine medicine, having the correct shape, colour, and imprint. *Imitation* products are falsifications that do not look like the genuine medicine, but claim or suggest a similar pharmacological effect. They can differ from the genuine product by shape, colour, imprint, or dosage form. As Viagra[®] and Cialis[®] are both tablets, all other dosage forms, like capsules, gels, and beverages, are by definition *Imitation*. All samples containing a new sildenafil analogue were placed in the main category *Analogue*, independently of their appearance or the presence of sildenafil. These samples were brought together in one main category in view of their similar risk profile. All samples that could not be categorised due to missing data fell into the main category *Others*.

The main categories *Counterfeit* and *Imitation* were divided into five subcategories, based on the differences in risks to public health related to the presence and content of the correct API (sildenafil or tadalafil).

In the Figures 1 - 11, the samples are depicted in several ways to illustrate trends in the type of samples. Figure 1 shows the number of Viagra and Cialis falsifications sent in for analysis per year and their total number. As can be seen, the number of Cialis falsifications is very small, only nine, and therefore the trend analysis for Cialis is limited. The Figures 2 - 10 concern only the Viagra falsifications. Figure 2 shows the total number of Viagra samples per subcategory. Figure 3 shows the number of samples per year in each main category. In Figure 4 the number of samples per year in each subcategory is given, whereas in Figure 5 the number of samples per subcategory is presented per year. The number of samples per subcategory per year can also be depicted as a percentage of the total amount of samples analysed per year. This is shown in five pie diagrams in Figures 6 - 10.

In Figure 11 the total number of Cialis samples per subcategory is given. In all figures, except Figure 1, the main category *Others* is left out, while these samples do not contribute to the trend analysis.

Table 1: Categories of samples.

Main category	Subcategory	Inclusion and exclusion criteria ^{1, 2)}
<i>Genuine</i>	<i>Genuine</i>	Cannot be distinguished from genuine medicine (see Table 2).
<i>Counterfeit</i>	<i>Professional counterfeit</i>	Appearance conform genuine medicine; content of correct API 90 - 110 % of declared value; no other APIs, not genuine medicine.
	<i>Non-professional counterfeit</i>	Appearance conform genuine medicine; content of correct API outside 90 - 110 % of declared value; no other APIs.
	<i>Mixed counterfeit</i>	Appearance conform genuine medicine; contains correct API and another API.
	<i>Fraudulent counterfeit</i>	Appearance conform genuine medicine; contains other API.
	<i>Placebo counterfeit</i>	Appearance conform genuine medicine; does not contain APIs.
<i>Imitation</i>	<i>Professional imitation</i>	Appearance not conform genuine medicine; content of correct API 90 - 110 % of declared value; no other APIs.
	<i>Non-professional imitation</i>	Appearance not conform genuine medicine; contains correct API, no other APIs.
	<i>Mixed imitation</i>	Appearance not conform genuine medicine; contains correct API and another API.
	<i>Fraudulent imitation</i>	Appearance not conform genuine medicine; contains other API.
	<i>Placebo imitation</i>	Appearance not conform genuine medicine; does not contain APIs.
<i>Analogue</i>	<i>Analogue</i>	Contains new sildenafil analogue.
<i>Others</i>	<i>Others</i>	Cannot be categorised due to missing data.

1) API: active pharmaceutical ingredient.

2) Appearance conform genuine medicine:

For Viagra[®]: diamond-shaped, blue tablet, imprint on one side “Pfizer”, on the other side “VGR 25”, “VGR 50”, or “VGR 100”.

For Cialis[®]: almond-shaped, yellow tablet, imprint only on one side “C 10” or “C 20”.

Table 2: Parameters of the main category Genuine.

	Viagra ^{® 1)}	Cialis ^{® 2)}
Appearance	diamond-shaped, blue tablet	almond-shaped, yellow tablet
Imprint	one side “Pfizer”, other side “VGR 25”, “VGR 50”, or “VGR 100”	only on one side “C 10” or “C 20”
Colour of the core	white	white
Size	25 mg: 9.2 x 6.7 mm 50 mg: 11.2 x 8.0 mm 100 mg: 14.1 x 10.2 mm	10 mg: 11.0 x 6.8 mm 20 mg: 12.3 x 7.6 mm
Weight	25 mg: 158 mg 50 mg: 317 mg 100 mg: 633 mg	10 mg: 260 mg 20 mg: 365 mg
Content of API	95 – 105 % of declared value	95 – 105 % of declared value
NIR correlation coefficient ³⁾	> 0.9980 with reference Viagra [®] library	> 0.9980 with reference Cialis [®] library

1) Size and weight obtained from Pfizer [4].

2) Size and weight are in-house observations.

3) Spectra with a correlation coefficient > 0.9980 are considered to be indistinguishable from the genuine product [2].

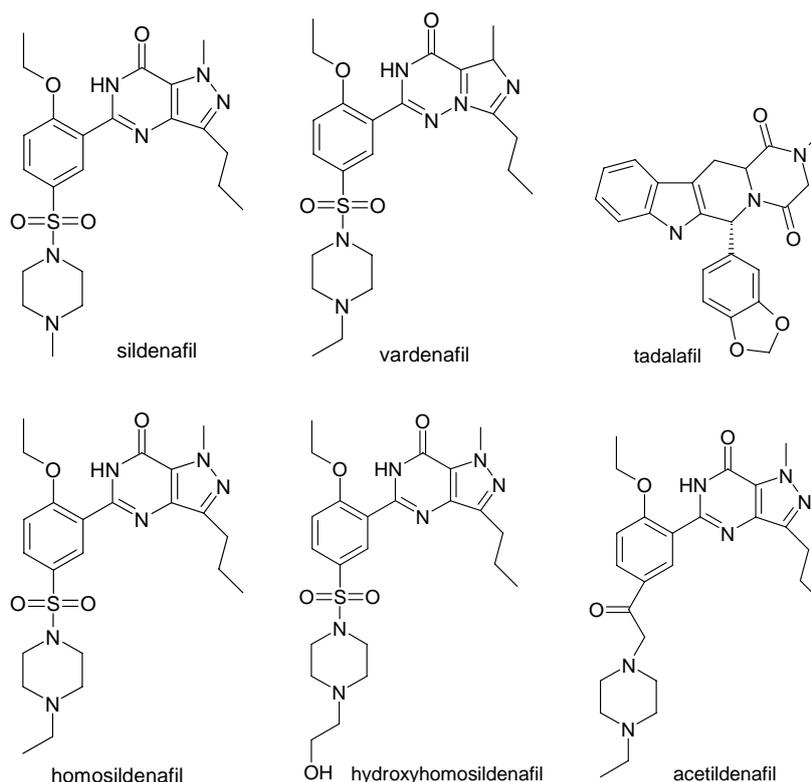
3. Results and discussion

3.1 Analytical results

3.1.1 Viagra falsifications

For all samples analysed during 2000-2004 the most important aspects, such as appearance, qualitative and quantitative data, NIR correlation, and categories are listed in Appendix 3. Most samples were quantitatively analysed for the presence of sildenafil or other APIs. Very often sildenafil was present, although in nearly all cases the amount was lower than declared. Other identified APIs were: amphetamine, clomifene, chloramphenicol, dipyrone, fluoxetine, tadalafil, yohimbine, γ -amino butyric acid (GABA), caffeine, L-arginine, indigotine, and quinine. Also combinations of these APIs with or without sildenafil were found.

Besides registered APIs unknown analogues of sildenafil [5] were identified in herbal products: homosildenafil, hydroxyhomosildenafil, and acetildenafil. These analogues are identified in samples by the authorities of the USA, Canada, Singapore, South Korea, and Japan [6-9] at approximately the same time. The structures of sildenafil, tadalafil, vardenafil, and the sildenafil analogues are depicted below. Vardenafil was not identified in any of the samples.



Structures of original active substances and analogues.

3.1.2 Cialis falsifications

The first sample in which tadalafil was identified, sample 6663 was analysed in 2002, even before the official MA of the product Cialis[®]. However, because of the blue colour, this

product was categorised as a Viagra imitation. It was not before the second half of 2003 that a Cialis falsification was sent in for analysis: it contained the correct amount of tadalafil, but was definitely not a look-alike, although the name Cialis was used. At the end of 2004 counterfeit Cialis was found in pharmacies and at pharmaceutical wholesalers. These counterfeits were first noticed in the United Kingdom, but after their alert these tablets were also found in the Netherlands, in other European countries, and even in Singapore and Australia. Analyses showed that these tablets contained tadalafil, sample 7541 and 7651, or a combination of sildenafil and tadalafil, samples 7510 and 7680, see Appendix 3.

3.2 General trends

After a modest start in 2000 and 2001, there is a large increase in the number of analysed Viagra falsifications, while only a few Cialis falsifications were analysed, as shown in Figure 1.

General trends are:

- the first appearance of sildenafil in a Viagra[®] falsification about 1½ year after granting the MA of Viagra[®];
- the first appearance of tadalafil in a falsification a month before granting the MA of Cialis[®], although it was classified as a Viagra imitation;
- the appearance of the first Cialis falsification about a year after granting the MA of Cialis[®];
- the appearance of genuine Viagra[®] in the illegal circuit in 2000;
- the appearance of *Professional imitations* of Viagra[®] in 2001;
- the appearance of a variety of products, supported by the success of Viagra[®], starting in 2002;
- the disappearance of genuine Viagra[®] from the illegal market in 2003;
- the appearance of sildenafil analogues in herbal products, starting in 2003 with a steep increase towards 2004;
- the imitation of the total presentation form: box, blister, tablet, and patient information leaflet;
- the appearance of technically good Cialis counterfeits, for tablets as well as for package, leaflet, and blister, in the official supply chain in 2004;
- the availability of raw material sildenafil and tadalafil, found during raids in 2003.

3.3 General risks to public health

The risks of falsifications to public health can be viewed from different perspectives: a) risks caused by the product itself, and b) risks caused by the information.

a) Risks caused by the product itself can be due to the manufacturing process. For registration of medicines Quality Control and Good Manufacturing Practice, inspected and approved by health authorities, is obligatory. The manufacturing of falsifications is neither inspected nor approved. This could lead to the presence of harmful impurities, toxic residual solvents, cross contamination, and bacterial contamination. Although some falsifications might look professional and even analysis might prove that the sample has a composition conform the original product, there is no guarantee that other batches will be identical. This must be interpreted as a risk to public health. A striking example is sample 6398. This

sample appeared to consist of tablets containing only sildenafil, sample 6398A, but the also included tablets containing sildenafil and clomifene, sample 6398B, see Appendix 3.

Other risks to public health caused by the product itself are pharmacological risks, caused by the composition. Such pharmacological risks arise if the falsification contains a quantity of sildenafil or tadalafil different from that in Viagra[®] or Cialis[®], respectively. If the falsification contains a lower amount, its pharmacological risk can be expected to be low. Higher pharmacological risks are expected when the content is higher. However, only a few of the analysed samples contained higher amounts of the relevant API.

Pharmacological risks of falsifications that contain other APIs than sildenafil or tadalafil depend on the identity of that API. If only caffeine is present, the pharmacological risks are low, but amphetamine, chloramphenicol, and dipyron can have serious pharmacological effects or side effects, depending on the amount present (see Appendix 1).

The pharmacological risk is always higher if combinations of more than one API are present. There is always a chance on an unforeseen pharmacological interaction between two or more APIs. To get an MA for a medicinal product containing more than one API, these interactions must have been studied. Consequently, the lack of evidence that there are no harmful interactions is a risk factor, even for apparently harmless combinations as sildenafil and caffeine.

A very high risk to public health are falsifications containing compounds that are expected to have pharmacological activity, based on their structural resemblance to an API, but that are not yet present in any drug product having an MA, and about which scientific data are absent in the literature. Little or nothing is known about their efficacy or safety.

The risk caused by the product itself can also be due to the dosage form: a tablet may be considered to be a pharmaceutical product, but a beverage in a can is harder to recognise as such by the consumer.

- b) Risks to public health of counterfeits and imitations can also be caused by incorrect, missing, or inadequate information, as presented on the drug product itself, e.g. by its imprint on a tablet, by information given on the package, or in the package insert. This type of risk was not purposely studied by the authors. The samples were received in different packages: sometimes in a complete package, consisting of a box, an information leaflet, a blister, and the dosage form, but very often only in a blister or an unlabeled plastic bag. It is unknown to the authors if consumers would receive the products in a similar package, so only general remarks can be made.

Serious risks to public health are falsifications that have incorrect information with respect to composition, dosage, side effects, contra indications, etc. This will mislead the user, increasing the chance that he exposes himself to dangerous medical situations: when medical help is needed the misleading information is an obstacle to provide the right and timely medical care needed in an emergency. Also, neither sildenafil nor tadalafil should be used by people with heart failure, not even if this is a latent medical problem. They should not be combined with products containing organic nitrate, such as “poppers”, a popular product at house parties. Especially when the product is marketed as purely natural, but contains a pharmacologically active compound, this is a serious risk, because most users will not attribute an unwanted effect to this product, because they believe that natural products are harmless by definition.

It is evident that missing information, for example on composition, dosage, side effects, or contra indications, bears the same risks to public health. This is also true for inadequate information, such as patient leaflets written in a foreign language, such as Spanish, Greek, or Chinese.

As most falsifications have a combination of product related risks and information related risks, their risk is higher than the sum of the individual risks. We assume that most users will not have any idea about the risks they expose themselves to.

3.4 Trends and risks by subcategory

Genuine samples cannot be distinguished from the genuine medicine based on appearance, size, weight, content of sildenafil, or correlation coefficients of the NIR analysis (see Tables 1 and 2). However, the probability that a sample fulfilling the criteria for inclusion in this main category is indeed a genuine medicine is high, in view of the high discriminatory power of NIR spectroscopy [2]. Samples falling in this main category are most likely genuine tablets found under “dubious” circumstances and probably obtained from the official supply chain by illegal acts (once Viagra[®] tablets were stolen from a truck and sold on the black market). Figures 3 and 4, show that the number of this type of Viagra samples diminishes over the years. This may be explained by greater care of the official supply chain to prevent theft. The only genuine Cialis[®], sample 7652, was sent in for comparison with falsifications.

Professional counterfeits are defined as counterfeits containing the correct amount of the correct API. Most Viagra samples in this subcategory were identified as “non-Pfizer” based on the NIR correlation coefficient, which was lower than 0.9980, for example sample 6622. In some cases of “VGR 100” products the weight was too low compared to Viagra[®], being just 570 mg instead of 633 mg (see Table 2, page 9, and Appendix 3, sample 6612). Cialis falsifications, samples 7510 and 7680, looked very professional, including the package, but contained tadalafil and sildenafil, and were consequently not classified as *Professional counterfeit*, but as *Mixed counterfeit*. As discussed above, even *Professional counterfeits* represent a potential risk to public health.

Non-professional counterfeits are defined as look-alikes with a substandard content of the correct API. Sample 7357A contained only 30 % of the amount of sildenafil suggested by the imprint. In 2002 - 2003 a steep increase in the number of samples in this subcategory is observed, in absolute as well as in relative amount, as can be seen in the Figures 4 and 6 - 10. This subcategory might be attractive for the illegal producer: the costs for buying the API are lower, whereas it might be hoped that the efficacy is still satisfactory by the placebo effect.

Mixed counterfeits are defined as counterfeits containing a mixture of the correct API and another API. There were no *Mixed counterfeits* seen in the Viagra falsifications. Two Cialis samples, 7510 and 7680, fell in this subcategory, containing tadalafil and sildenafil. The amount of these two APIs was different in these cases. As discussed above, every combination of pharmacologically active substances that is not evaluated for their interaction represents a risk to public health.

Fraudulent counterfeits are defined as counterfeits containing only a “wrong” API. “Wrong” APIs identified in Viagra falsifications were dipyrone, chloramphenicol, yohimbine, caffeine,

and quinine, see Appendix 3. *Fraudulent counterfeits* of Cialis were up till now not encountered.

Apart from the general health risks of using counterfeits, there is the risk associated with the pharmacological effects of the “wrong” API. The pharmacological effects of the APIs found are summarised in Appendix 1. There are relatively harmless APIs, such as caffeine. But other APIs found are indeed harmful. For instance, sample 6755 contains 317 mg dipyrone, which should only be used for the relief of severe pain if no alternative is available, because of its serious adverse drug reactions [10]. Apart from the risks associated with the pharmacological effects of the API, an additional risk seems to be that the pharmacological action of the API might differ from the expected effects based on the label claim.

Surprisingly, after a steep increase in *fraudulent counterfeits* in 2002 - 2003, there is a steep decrease in 2004, see Figures 4 and 6 - 10. Could it be that counterfeit producers have become reluctant to use APIs with, to them, unknown pharmacological effects, as they do not want to cause health damage by their counterfeits?

Professional imitations are defined as being not a look-alike of the genuine medicine, but containing 90 - 110 % of the amount of API indicated by the name or imprint, such as Caverta 50 and Kamagra 100. Samples 7004 and 7673 were the only Cialis falsifications, all the others in this subcategory were Viagra falsifications. Examples are: sample 6232, Caverta; and sample 7223, Kamagra. The absolute number of samples in this subcategory is more or less stable over the years 2001 - 2003, but with an increase in 2004, as can be seen in Figure 4. As these products are mostly produced by official pharmaceutical companies in the Far East, where patent rights from Europe and the USA are not respected, a decrease in production of these samples is not to be expected. The decrease of the relative number from 46 % in 2001 to 18 % in 2004 (see Figure 5), is due to the increase of samples in other subcategories. The risk of these products is limited to the risk of a quality control system that might have less strict requirements than the European or American quality control system. This is illustrated by samples 6399, 7002, 7223, 7270, 7272, and 7669, all Kamagra 100, containing sildenafil varying from 87 to 104 % of the declared amount.

Non-professional imitations are defined as not look-alikes of the genuine medicine, but containing the correct API. However, when strength was indicated, its amount was outside the range of 90 - 110 %. Only one Cialis falsification, sample 7675, was found in this category, all the others were Viagra falsifications. Examples are sample 6299, Shen Bao San Bian Li, and sample 6762, Erexer. About 30 % of all Viagra *Imitations* fall in this subcategory. The number of samples shows an upward trend over the years, indicating that ever more producers want to benefit from the Viagra[®] success. Apart from the general risks of substandard counterfeits, other risks are encountered in this subcategory: absence of information, sample 6098, V-king; information in Chinese, sample 6297, Jipinweigewang; incorrect therapeutic indication, sample 7052, “Afrodisiac, 60 mg, girls”.

Mixed imitations are defined as not look-alikes of the genuine medicine, containing the correct API in combination with another API, such as sildenafil in combination with clomifene, tadalafil, yohimbine and GABA, and caffeine. In this subcategory only Viagra falsifications were found. In the years 2000 - 2004, a product named Sigra was analysed 33 times because the composition of this product varied. Ten samples (samples 6667 - 6670, 6820, 6821, 6858, 6860, 6933, and 6934) were categorised as *Mixed imitation* containing besides sildenafil also yohimbine and GABA, the other 23 samples were *Fraudulent imitations* (6663 - 6666, 6712 - 6725, 6822, 6823, 7125, and 7126).

The public health risks associated with this subcategory are not only attributed to the pharmacological effects of the second API. Additional risks depend on the interactions of the APIs. For instance, there is probably little known about the interactions of sildenafil and clomifene, because the former is intended for use by men and the latter for use by women; so, this combination represent a risk in itself, additionally to the risk of taking only clomifene for men.

Fraudulent imitations do not look like the genuine medicine and also do not contain the correct API, although the name or claim suggests a similar effect. However, they contain a different API, such as amphetamine, fluoxetine, yohimbine, or caffeine, as is shown in Appendix 1. The first appearance of tadalafil was noticed in this subcategory, in the product Sigra mentioned above, samples 6663 - 6666.

Fraudulent imitations represent about 30 % of all *Imitations*. They show a strong upward trend over the years, except for 2004, for which no explanation could be given (see Figures 4 and 5).

The samples in this subcategory suggest a better sexual performance, but some of them contain APIs with pharmacologically effects not related to erectile dysfunction. For instance, sample 5214 is diamond-shaped pink tablet with imprints “Pfizer” and “VGR 50”, suggesting a Viagra tablet for women, but containing amphetamine. Sample 7435, “Lady Viagra”, contains fluoxetine, an antidepressant. Sample 6756 contains a high amount of dipyrone: 338 mg per tablet. Amphetamine, dipyrone and fluoxetine all can have serious adverse drug reactions, see Appendix 1.

Placebo imitations do not look like the genuine medicine and do not contain any API, although the name or claim is usually very suggestive. Examples are: sample 7134, 4 Pleasure; sample 7147, Potency total; and sample 7228, Penis XL. Only Viagra falsifications fell in this subcategory. No samples were found in 2001 and 2002; in the other years this subcategory contributed for about 10 % of the total amount as shown in Figures 6 - 10. This subcategory represents only small public health risks. They have the general risks of products of which the manufacture and composition is not controlled by governmental bodies.

Analogues were defined as all samples containing new sildenafil analogues. Representative examples are: samples 6893 and 6935, Julang, containing homosildenafil; sample 7293, Satibo, and sample 7385, Viacaps, both containing hydroxyhomosildenafil; sample 7235, Libido Forte Herbal Supply, samples 7325, 7326, 7445, and 7450 - 7465, Libidfit, and samples 7436 and 7437, Herbal drink, all containing acetildenafil.

The analogues were identified in different type of dosage forms, all with a herbal claim: Julang are “anti-fatigue” tablets; Libido Forte Herbal Supply are capsules; Satibo are capsules in a blister in a glamorous sardine tin; Viacaps are capsules; samples 7436 and 7437 are herbal drinks with lemon or cassis taste in a can; Libidfit are capsules in a blister in a box, with a varying composition of herbs declared.

This main category shows a strong upwards trend over the last two years, as can be seen from Figures 3 and 4. The reason for the appearance of analogues of sildenafil could be threefold: a) the analogue is possibly not covered by the patent for sildenafil; b) the analogue is not registered as an API, and therefore the product might not be illegal; c) the analogue complicates analysis and therefore prosecution. The appearance of these compounds indicates a trend towards “designer” drugs: modifications to existing, registered molecules. As the analogues were identified at almost the same time throughout the world, it can be concluded that the synthesis of these new substances is performed on a large scale.

This main category represents serious risks to public health. As the analogues are structurally related to sildenafil they are most probably biologically active, but their pharmacological and toxicological profile is not established, and therefore they may have unpredictable effects and interactions. In all these falsifications the risk of pharmacological effects is combined with the declaration of herbs, suggesting “natural” or “herbal” and therefore “harmless”. Also some of the dosage forms used, such as drinks with the taste of fruit juice, add to the suggestion of harmless “food supplements”.

In this main category also samples were found having a changing composition with respect to their APIs. The samples 6807, 7141, and 7222 “Libido Forte” contained sildenafil, but sample 7235, also named “Libido Forte” contained acetildenafil. The only visual changes in this illegal medicine were a different colour of capsules and a different package. However, the blister was identical in all four cases. This represents an additional risk to the user: consumers that used the product before without problems might now be confronted with unexpected pharmacological effects – without any knowledge that this might be caused by a major change in the composition of this “herbal food supplement”.

3.5 Conclusions and recommendations

Although this survey is limited to the samples analysed, which -maybe- are not an adequate reflection of the nature and number of falsifications on the illegal market, we conclude that users of counterfeit medicines are exposed to health risks of which they are most probably unaware. This holds for counterfeits as well as for imitations. Especially products, containing unexpected APIs or new sildenafil analogues with an unknown toxicological profile, bear high risks for the consumers. Surveys of the market are important to observe trends, and to discover new compounds and new risks.

With respect to the responsibility of the health authorities towards falsifications of medicines, there is always the dilemma between the freedom of the individual to take care of his own life, in a way he wants, for instance by taking “food supplements” and “herbal products”, and the prevention of health damage of the users of these products. However, it is the responsibility of the government in cooperation with the official supply chain to protect the patient against counterfeited medicines, because of the risks.

In former days, there was an obligation for parallel importers to test each imported batch. However, the present EU rules forbid member states to require retesting batches that were released in another member state. The infiltration of the Cialis counterfeit in the official supply chain shows the weakness of this system.

We recommend:

- Reporting the risks of falsifications to the broad public, not as a general warning “not to use illegal medicines”, but by presenting actual cases, for instance the “herbal” imitations containing “chemically” pharmacologically active substances.
- Well structured monitoring, by sampling and analysing products, in order to provide a representative view of the illegal market.
- Combination and coordination of the activities of several governmental bodies to come to a more coherent overview on the trends and risks of falsifications of medicines.

Figures

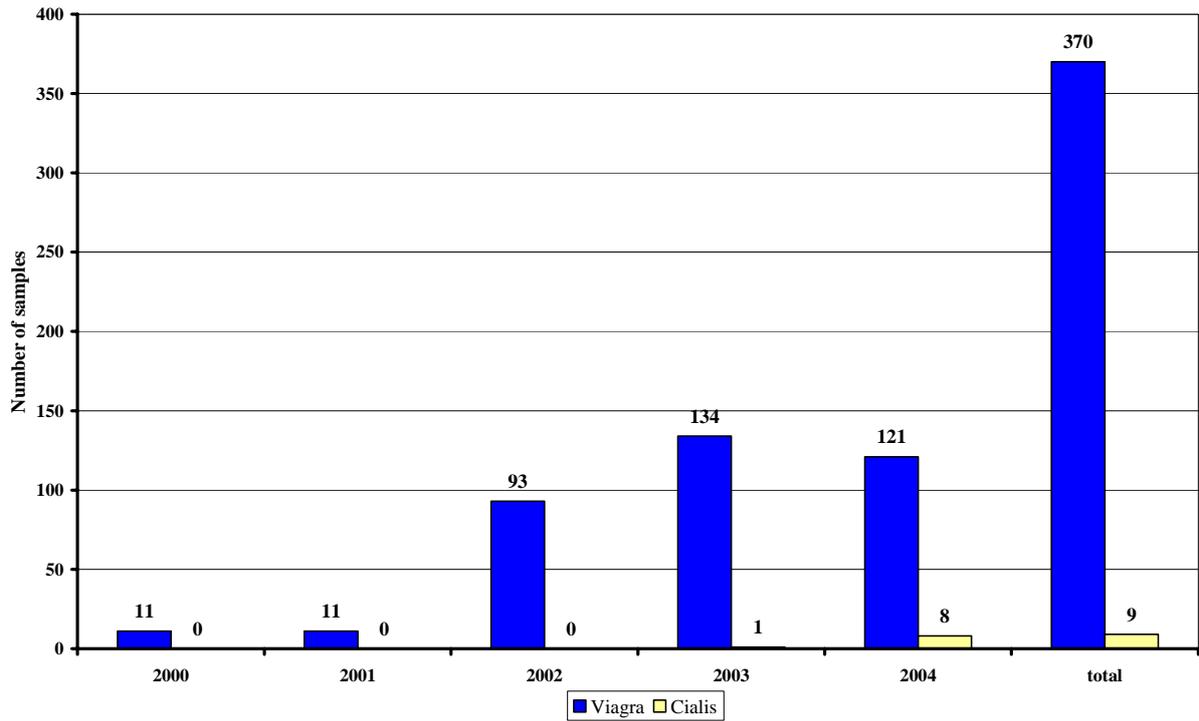


Figure 1: Total number of Viagra and Cialis related samples per year.

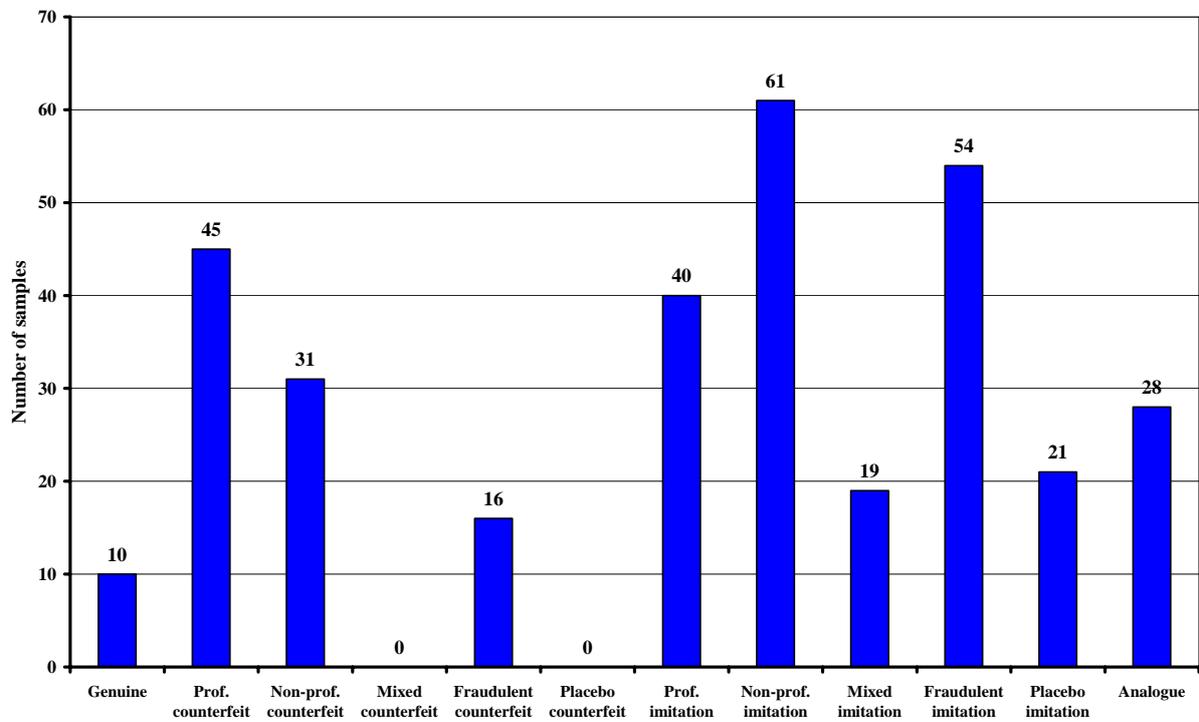


Figure 2: Total number of Viagra related samples per subcategory.

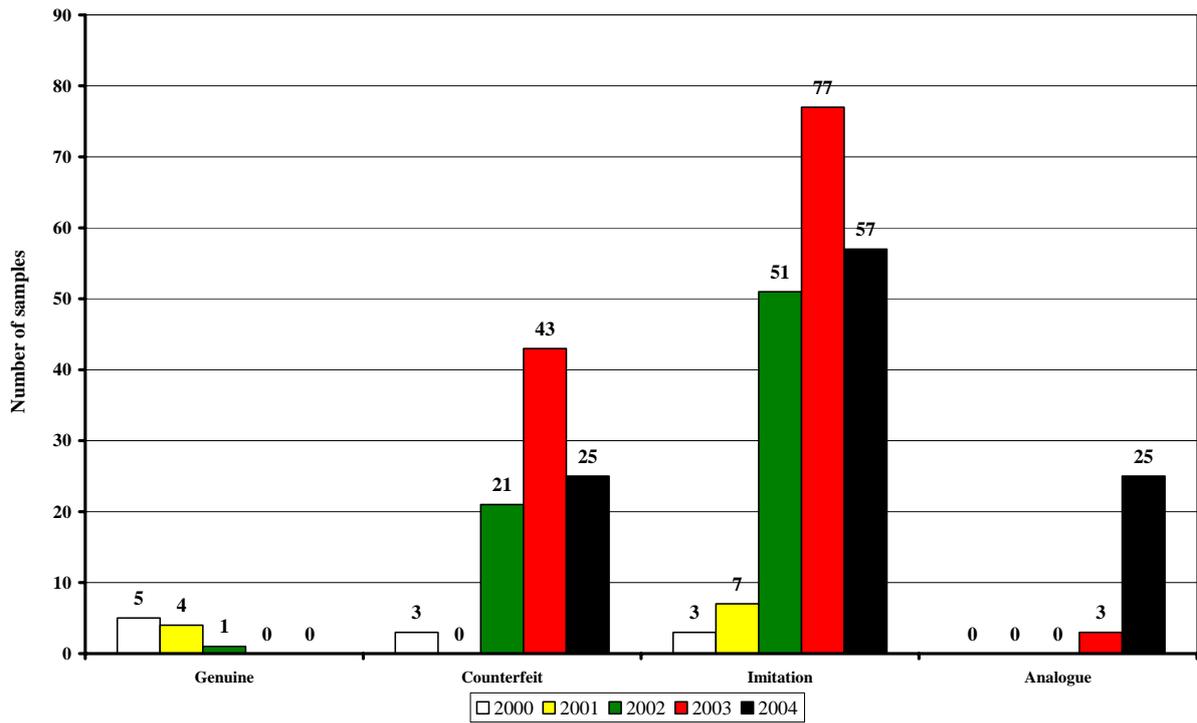


Figure 3: Number of Viagra related samples per year per main category.

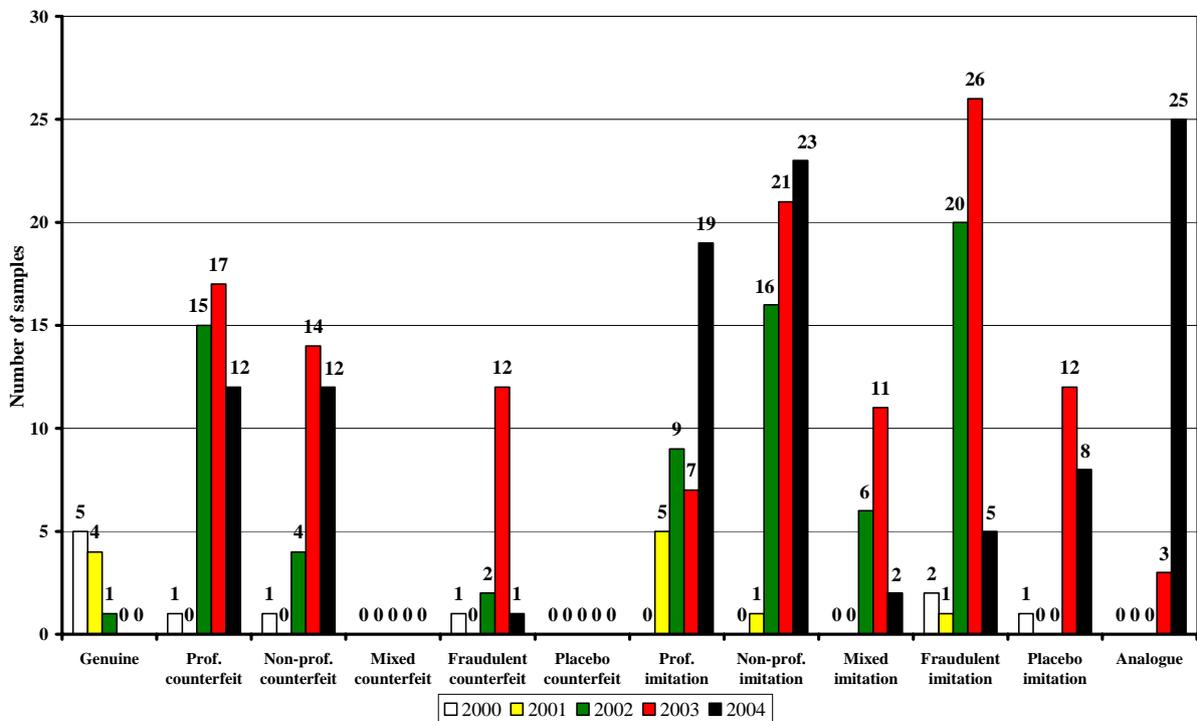


Figure 4: Number of Viagra related samples per year per subcategory.

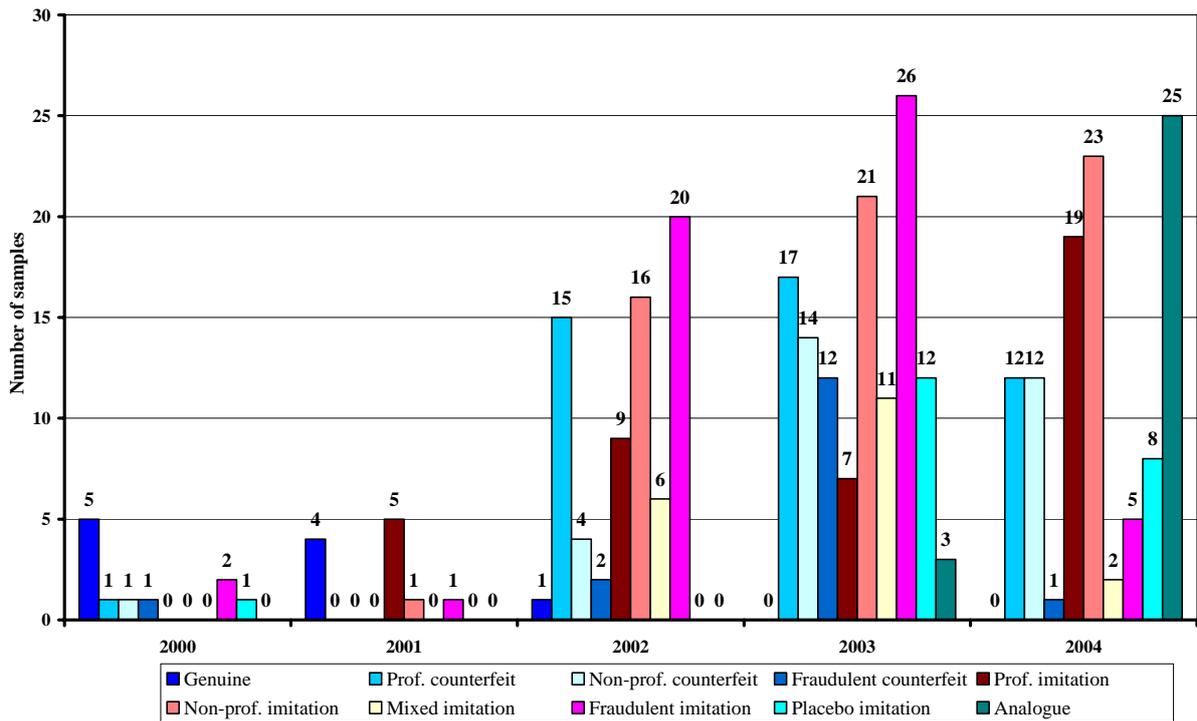


Figure 5: Number of Viagra related samples per subcategory per year.

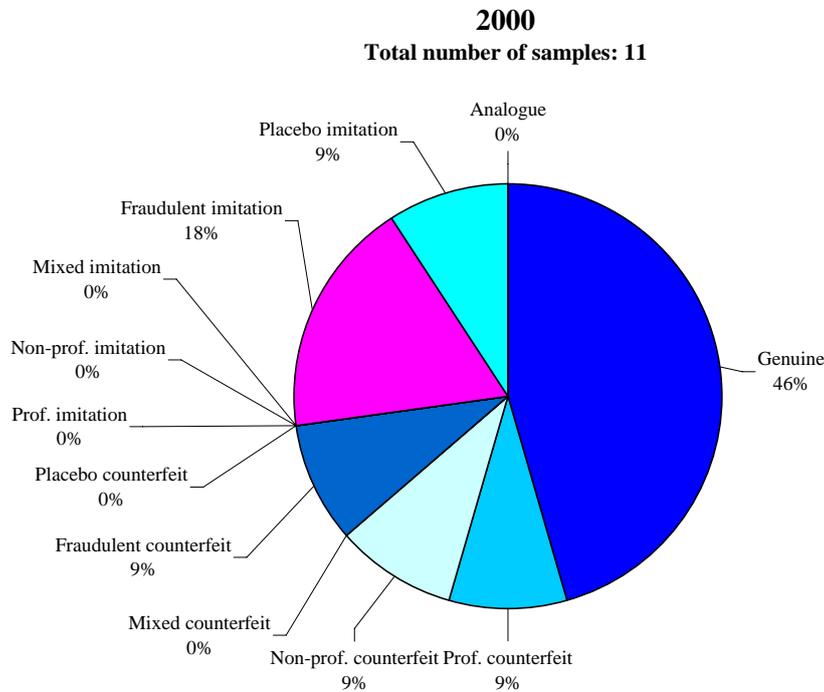


Figure 6: Percentage of Viagra related samples in each subcategory in 2000.

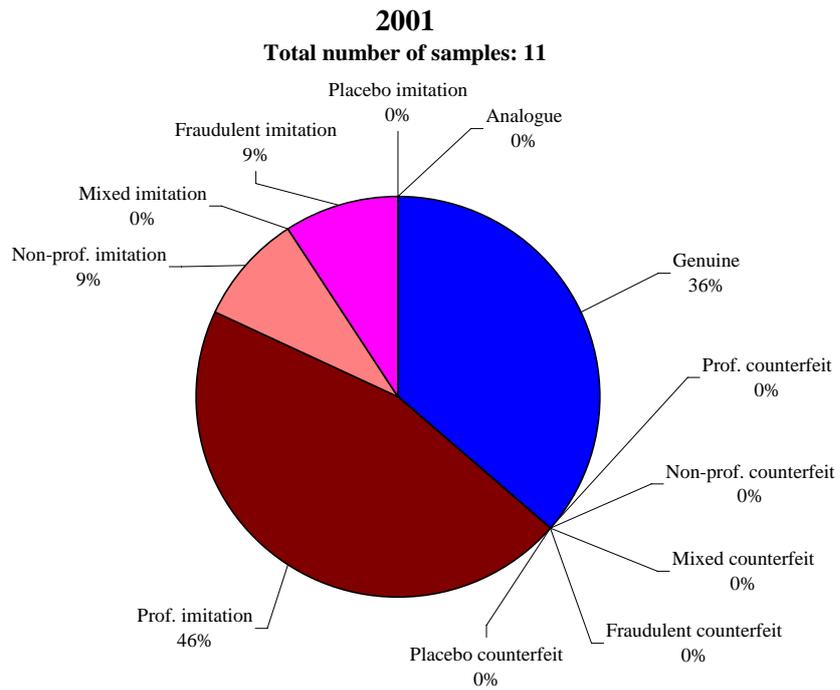


Figure 7: Percentage of Viagra related samples in each subcategory in 2001.

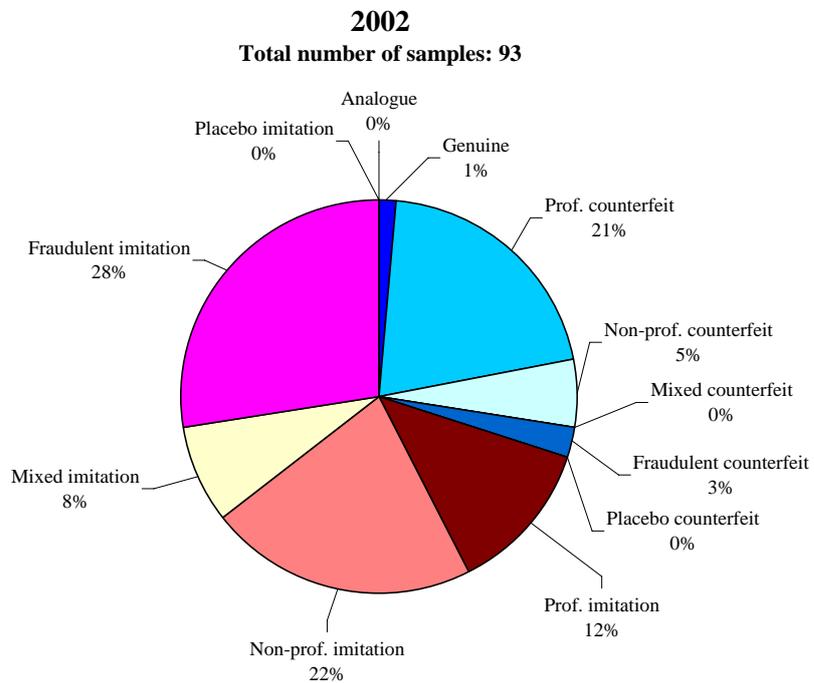


Figure 8: Percentage of Viagra related samples in each subcategory in 2002.

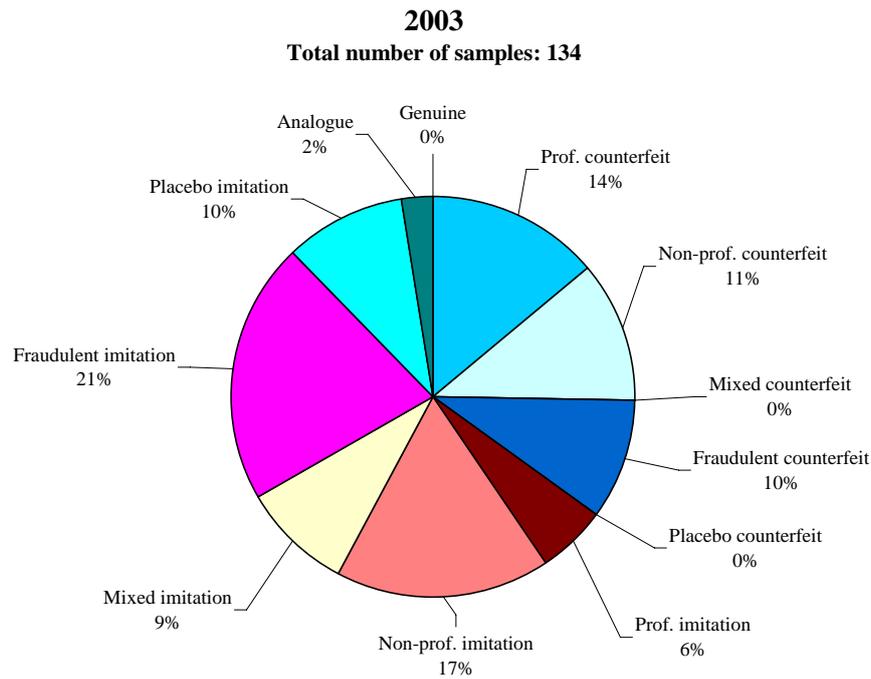


Figure 9: Percentage of Viagra related samples in each subcategory in 2003.

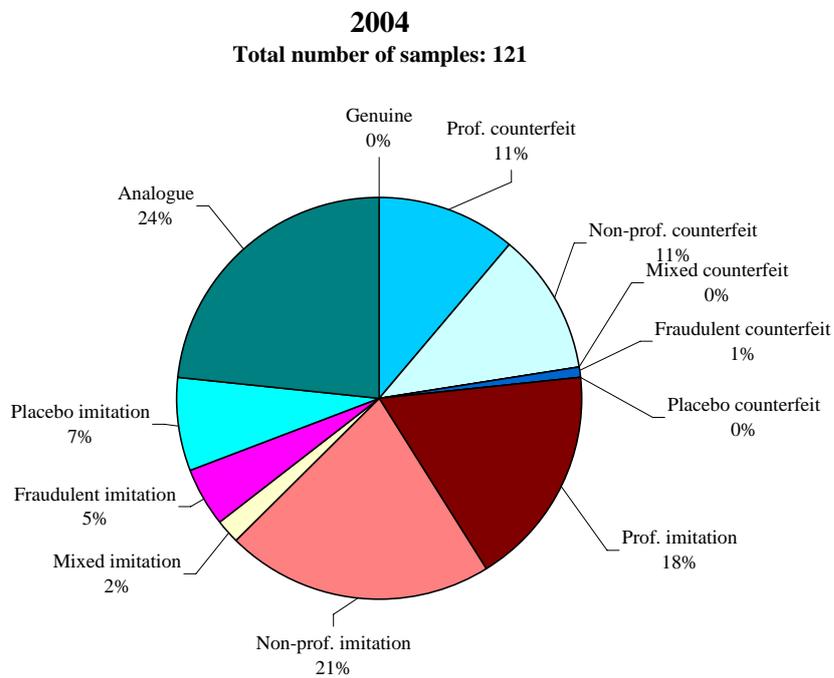


Figure 10: Percentage of Viagra related samples in each subcategory in 2004.

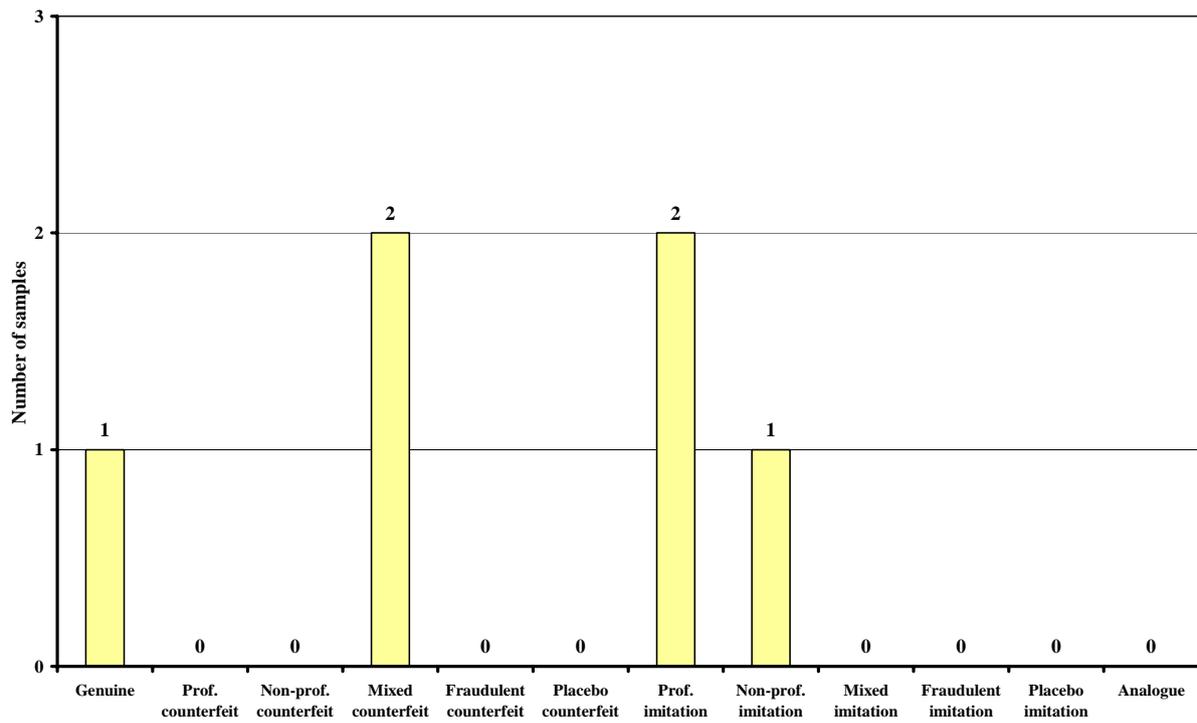


Figure 11: Number of Cialis related samples per subcategory.

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Appendix 1: Relevant Adverse Drug Reactions (ADRs) of APIs found in falsifications.

Source: Martindale Extra Pharmacopoeia [10].

Sildenafil	ADRs most commonly reported from sildenafil are headache, flushing, and dyspepsia. There may be visual disturbances, dizziness, and nasal congestion. Other ADRs reported include diarrhoea, vomiting, swelling of the eyelids, pain and redness of the eyes, epistaxis muscle pain, skin rashes, urinary-tract infection, syncope, cerebrovascular haemorrhage, and transient ischaemic attack. Priapism has also occurred. There have also been reports of palpitations and serious cardiovascular events, including sudden cardiac death, associated with the use of sildenafil.
Tadalafil	As for Sildenafil. Visual disturbances may occur less frequently with tadalafil than with sildenafil.
Vardenafil	As for Sildenafil. Photosensitivity has been reported with vardenafil.
Yohimbine	A literature study gave a warning about the potential ADRs, including anxiety, manic reactions, bronchospasm and a lupus-like syndrome. Interactions with tricyclic antidepressants and with phenothiazines might also occur.
Gamma-aminobutyric acid (GABA)	About half of all patients experience ADRs. The most common are drowsiness and fatigue. Other CNS-related adverse effects include dizziness, nervousness, irritability, headache, nystagmus, ataxia, paraesthesia, tremor, and impaired concentration. Less commonly, confusion and memory disturbances have been reported. Other reported ADRs include weight gain, gastrointestinal disturbances, oedema, alopecia, angioedema, urticaria, and skin rash. Haemoglobin and liver enzyme values may be decreased. Rarely marked sedation, stupor and confusion, together with other symptoms suggestive of encephalopathy, have occurred. About one-third of all patients have developed irreversible visual field defects, ranging from mild to severe and usually occurring after months or years of therapy. Blurred vision, diplopia, or nystagmus are somewhat less common. Retinal disorders such as peripheral retinal atrophy, or very rarely optic neuritis or atrophy have also been reported.
(Dex)amphetamine	ADRs are commonly symptoms of overstimulation of the CNS and include insomnia, night terrors, nervousness, restlessness, irritability, and euphoria that may be followed by fatigue and depression. There may be dryness of the mouth, anorexia, abdominal cramps and other gastrointestinal disturbances, headache, dizziness, tremor, sweating, tachycardia, palpitations, increased or sometimes decreased blood pressure, altered libido, and impotence. Psychotic reactions have occurred, as has muscle damage with associated rhabdomyolysis and renal complications. Rarely, cardiomyopathy has occurred with chronic use. In children, growth retardation may occur during prolonged treatment. In acute overdose, the ADRs are accentuated and may be accompanied by hyperpyrexia, mydriasis, hyperreflexia, chest pain, cardiac arrhythmias, confusion, panic states, aggressive behaviour, hallucinations, delirium, convulsions, respiratory depression, coma, circulatory collapse, and death. Individual patient response may vary widely and toxic manifestations may occur with quite small overdoses. Tolerance can develop to some of dexamphetamine's central effects leading to increased doses and habituation. Abrupt cessation after prolonged treatment or abuse of amphetamines has been associated with extreme fatigue, hyperphagia, and depression. However, it is generally accepted that the amphetamines, although widely abused, are not associated with substantial physical dependence. Abuse of amphetamines for their euphoriant effects has resulted in personality changes, compulsive and stereotyped behaviour, and may induce a toxic psychosis with auditory and visual hallucinations and paranoid delusion.
Clomifene citrate	The incidence and severity of ADRs clomifene citrate tend to be related to the dose used. The most commonly reported ADR are reversible ovarian enlargement and cyst formation, vasomotor flushes resembling menopausal symptoms, and abdominal or pelvic discomfort or pain, sometimes with nausea or vomiting. Transient visual disturbances such as after-images and blurring of vision may occur, and there have been rare reports of cataracts and optic neuritis. Skin reactions such as allergic rashes and urticaria have occasionally been reported and reversible hair loss has been reported rarely. CNS disturbances have included convulsions, dizziness, lightheadedness, nervous tension, fatigue, vertigo, insomnia, and depression. Abnormalities in liver function tests and jaundice have sometimes been reported.
Dipyron	Use of dipyron is associated with an increased risk of agranulocytosis and with shock. Because of the risk of serious ADRs, in many countries its use is considered justified only in severe pain where no alternative is available or suitable.
Quinine	Quinine may give rise to cinchonism, characterised in its mild form by tinnitus, impaired hearing, headache, nausea, and disturbed vision, with, in its more severe manifestations, vomiting, abdominal pain, diarrhoea, and vertigo. Cinchonism may also occur after small doses in patients hypersensitive to quinine. Other effects include fever, skin rashes, and dyspnoea. Angioedema may also occur and asthma can be precipitated. Thrombocytopenia and other blood disorders have been reported. Thrombocytopenic purpura has been associated with quinine hypersensitivity. Haemoglobinuria occurs rarely. Other ADRs of quinine include hypoglycaemia,

	hypoprothrombinaemia, and renal failure. The main symptoms of overdosage, which can be fatal, include gastrointestinal effects, oculotoxicity, CNS disturbances, and cardiotoxicity. Visual disturbances including sudden blindness are usually slowly reversible but there may be residual damage. Quinine can produce cardiovascular toxicity similar to that seen with quinidine including conduction disturbances, arrhythmias, anginal symptoms, and hypotension leading to cardiac arrest and circulatory failure.
L-arginine	For the oral use, there are no adverse drug reactions mentioned.
Fluoxetine	ADRs reported with fluoxetine include dry mouth and gastrointestinal disturbances such as nausea, vomiting, dyspepsia, constipation, and diarrhoea. Anorexia and weight loss may also occur. Neurological side-effects have included either anxiety, restlessness, nervousness, and insomnia, or drowsiness and fatigue; headache, tremor, dizziness, convulsions, hallucinations, confusion, agitation, extrapyramidal effects, depersonalisation, panic attacks, sexual dysfunction, and symptoms suggestive of a serotonin syndrome have also occurred. Fluoxetine may be associated with increased suicidal ideation. Excessive sweating, pruritus, skin rashes, photosensitivity, and urticaria have also been reported. Angioedema and anaphylactoid reactions have occurred. In some patients who have developed rashes while taking fluoxetine, systemic hypersensitivity reactions involving the lungs, kidneys, or liver, and possibly related to vasculitis, have developed. Hyponatraemia, possibly due to inappropriate secretion of antidiuretic hormone, has been associated with the use of antidepressants, particularly in the elderly. Hyperprolactinaemia and galactorrhoea have occurred, as have changes in blood sugar, in patients receiving fluoxetine. Arthralgia and myalgia have been reported and there have also been cases of abnormal vision, orthostatic hypotension, and urinary retention. Abnormal liver function tests have been reported rarely. Fluoxetine have occasionally been associated with bleeding disorders and other effects on the blood. In overdosage nausea, vomiting, and excitation of the CNS are considered to be prominent features; death has been reported.
Indigotine (indigo carmine)	Indigo carmine may cause nausea, vomiting, hypertension, and bradycardia, and occasionally, hypersensitivity reactions such as skin rash, pruritus, and bronchoconstriction.
Chloramphenicol	Chloramphenicol may cause serious and sometimes fatal ADRs. Some of its toxicity is thought to be due to effects on mitochondrial protein synthesis. The most serious ADR of chloramphenicol is bone-marrow depression, which can take two different forms. The first is a fairly common dose-related reversible depression. The second and apparently unrelated form of bone-marrow toxicity is severe irreversible aplastic anaemia. This is fairly rare and is not considered to be dose-related. Prolonged oral use of chloramphenicol may induce bleeding, either by bone-marrow depression or by reducing the intestinal flora with consequent inhibition of vitamin K synthesis. Haemolytic anaemia has occurred in some patients with the Mediterranean form of glucose 6-phosphate dehydrogenase deficiency, but is rare in patients with milder forms of the deficiency. Peripheral as well as optic neuritis has been reported in patients receiving chloramphenicol, usually over prolonged periods. Although ocular symptoms are often reversible if treatment is withdrawn early, permanent visual impairment or blindness has occurred. Other neurological symptoms have included encephalopathy with confusion and delirium, mental depression, and headache. Ototoxicity has also occurred, especially after the use of ear drops. Hypersensitivity reactions including rashes, fever, and angioedema may occur especially after topical use; anaphylaxis has occurred but is rare. Jarisch-Herxheimer reactions may also occur. Gastrointestinal symptoms including nausea, vomiting, and diarrhoea can follow oral use. Disturbances of the oral and intestinal flora may cause stomatitis, glossitis, and rectal irritation.
Hydroxyhomosildenafil	No information available.
Homosildenafil	No information available.
Acetildenafil	No information available.

Appendix 2: Declaration of quality control

Undersigned states herewith:

RIVM-KCF, Centre for Quality of Chemical-Pharmaceutical Products is in compliance with the accreditation criteria as laid down in ISO/IEC 17025: 1999 (accreditation number L131). The accreditation has been granted by the Dutch Accreditation Council RvA for the first time on 24 February 1994 and is valid until 24 February 2006. The accreditation covers the quality system as well as the specific activities as described in an authorized annex. This annex is available at RIVM, KCF or on the website of the Dutch Accreditation Council RvA (www.rva.nl).

Quality control officer:

Name: E.M. Stofberg

Laboratory: RIVM-KCF

Date: Signature:

6 july 2005
Em Stofberg

Appendix 3: Analytical results of Viagra and Cialis falsifications

Legend to the table:

The following columns are defined:

Sample number: Unique internal identification number given to the sample sent in for analysis.

Product name: Name under which the samples were received, or given by the project leader for identification purposes. The product names included in the table do not necessarily represent the true name of the product.

Year of analysis: Represents the year the sample was received. This is also regarded to be the year of analysis.

Active substance: Presence or absence of pharmacologically active substances.

- A number in a specific column: quantitative amount in mg/dosage unit (or in some specific cases as a %).
- "T": trace of the substance is present.
- • : substance is identified, but not quantified.
- n.d.: substance is not detected, although qualitative analyse was carried out.
- blank field: sample was not analysed for the presence of the substance.

Appearance: The visual appearance of the dosage form.

NIR: NIR correlation coefficients of the sample with the relevant reference library (Viagra or Cialis) are given. The following limits were used for the interpretation of the NIR results:

> 0.9980:	Identical
0.99 - 0.9980:	Strongly similar
0.98 - 0.99:	Similar
0.95 - 0.98:	Slightly similar
< 0.95:	Dissimilar

Analytical results of Viagra falsifications

Sample number	Product name	Year of analysis	Active substance (mg/dosage unit)																Appearance	NIR	Classification		
			Sildenafil	Homosildenafil	Hydroxyhomosildenafil	Acetildenafil	Tadalafil	Vardenafil	Yohimbine	GABA	(Dex)Amphetamine	Caffeine	Clomifene citrate	Dipyrrone	Quinine	L-arginine	Fluoxetine	Indigotine				Chloramphenicol	Others
5002	Viagra	2000	32																		diamond-shaped, blue spotted; Pfizer/VGR 50; uncoated	0,8902	Non-prof. counterfeit
5109	Viagra 100 mg	2000	100																		diamond-shaped, blue; Pfizer/VGR 100; Spanish package	0,9994	Genuine
5159	Viagra 50	2000	47																		diamond-shaped, blue; Pfizer/VGR 50; Spanish package	0,9989	Genuine
5162	Viagra 50	2000	48																		diamond-shaped, blue; Pfizer/VGR 50	0,9991	Genuine
5211	Viagra 100 mg	2000	95																		diamond-shaped, blue; Pfizer/VGR 100; white core	0,9961	Prof. counterfeit
5212	Viagra 100 mg	2000	96																		diamond-shaped, blue; Pfizer/VGR 100; white core	0,9981	Genuine
5213	Viagra 100 mg	2000	96																		diamond-shaped, blue; Pfizer/VGR 100; white core	0,9985	Genuine
5214	Viagra 50 mg	2000																			diamond-shaped, pink; Pfizer/VGR 50	0,7367	Fraudulent imitation
5471	Blue tablet	2000								10											diamond-shaped, blue; Pfizer/VGR 50; white core	0,7683	Fraudulent counterfeit
5472	Pink tablet	2000								0,4											diamond-shaped, pink; Pfizer/VGR 50; uncoated	0,6263	Fraudulent imitation
5564	Viagra 50	2000	n.d.																		diamond-shaped, blue; 50 on one side; uncoated	0,9531	Placebo imitation
5551	Viagra 100	2001	103																		diamond-shaped, blue; Pfizer/VGR 100; white core	0,9990	Genuine
5552	Viagra 100	2001	105																		diamond-shaped, blue; Pfizer/VGR 100; white core	0,9994	Genuine
5608	Viagra 100 mg	2001	104																		diamond-shaped, blue; Pfizer/VGR 100; white core	0,9993	Genuine
5609	Viagra 100 mg	2001	103																		diamond-shaped, blue; Pfizer/VGR 100; white core	0,9993	Genuine
5810	Two blue balls	2001								2											round, light blue; no imprint; white core	too small for NIR	Fraudulent imitation
6096	Androz-100	2001	99																		round, blue; no imprint; white core	0,7290	Prof. imitation
6097	Androz-100	2001	99																		round, blue; no imprint; white core	0,7296	Prof. imitation
6098	V-king	2001	28																		red capsule with brown powder	not analysed	Non-prof. imitation
6114	Vigrex	2001	99																		diamond-shaped, blue; VGX/100; white core	0,9668	Prof. imitation
6163	Penegra 100	2001	91																		diamond-shaped, old rose; V/100	0,9529	Prof. imitation
6175	Edegra 50	2001	47																		round, blue; no imprint; score on one side	0,9261	Prof. imitation
6231	Erecto-50	2002	50																		oval, blue; no imprint; white core; score on one side	0,9600	Prof. imitation
6232	Caverta 100	2002	102																		triangular, red; 100; white core	0,9763	Prof. imitation
6295	Blue round tablet	2002	50																		round, blue; no imprint; white core; with score	0,9170	Non-prof. imitation
6297	Jipinweigewang	2002	59																		diamond-shaped, blue; VG/VG; white core	0,7930	Non-prof. imitation
6298	Crvel Elder Brother	2002	64																		diamond-shaped, pink with gray spots; KG/KG; light brown core	0,9329	Non-prof. imitation
6299	Shen Bao San Bian Li	2002	53																		diamond-shaped, blue; Chinese characters/150 mg; white core	0,8188	Non-prof. imitation
6300	Blue Heart	2002	51																		diamond-shaped, blue; Chinese characters/VAR 120; white core	0,7348	Non-prof. imitation
6301	LZI	2002	60																		diamond-shaped, blue; VG/150 mg; white core; thin coating	0,7923	Non-prof. imitation
6302	Dream of Blue	2002	51																		diamond-shaped, blue; Chinese characters/VAR 120; white core	0,7733	Non-prof. imitation
6303	Zhi Zhao Shang	2002	52																		diamond-shaped, blue; MOUNT/MIAOGE; green blue core	0,9403	Non-prof. imitation
6304	Libo	2002	43																		diamond-shaped, blue; VG/VG; white core	0,7403	Non-prof. imitation
6386	Vega tablet	2002	48																		diamond-shaped, blue; ASIA; white core	0,9803	Non-prof. imitation
6398 ¹⁾	Sildenafil citrate (blue tablets)	2002																			diamond-shaped, blue; 100		
A		2002	73																		diamond-shaped, blue; 100; white core; thin coating	0,9706	Non-prof. imitation
B		2002	21																		diamond-shaped, blue; 100; white core; thin coating	0,9496	Mixed imitation
6399	Kamagra	2002	87																		diamond-shaped, blue; symbol/KGR 100; white core; thin coating	0,9848	Non-prof. imitation
6400	Blue tablets with imprint: Pfizer	2002	n.d.																		diamond-shaped, blue; Pfizer/VGR 50; white core; thin coating	0,7034	Fraudulent counterfeit
6420	Pink tablet with imprint: Pfizer	2002	n.d.																		diamond-shaped, pink; Pfizer/VGR 50; light pink core	0,8239	Fraudulent imitation
6459	Caverta 50	2002	50																		triangular, red	0,9712	Prof. imitation

Sample number	Product name	Year of analysis	Active substance (mg/dosage unit)															Appearance	NIR	Classification				
			Sildenafil	Homosildenafil	Hydroxyhomosildenafil	Acetildenafil	Tadalafil	Vardenafil	Yohimbine	GABA	(Dex)Amphetamine	Caffeine	Clemetine citrate	Dipyrrone	Quinine	L-arginine	Fluoxetine				Indigotine	Chloramphenicol	Others	
6503	Viagra	2002	45																		diamond-shaped, blue; Pfizer/VGR 100; white core	0,8926	Non-prof. counterfeit	
6504	Caverta 50	2002	52																		triangular, red; 50	0,9653	Prof. imitation	
6505	Caverta 50	2002	52																		triangular, red; 50	0,9706	Prof. imitation	
6520	Sildenafil citrate tablet I	2002	•																		diamond-shaped, blue; 100; white core	0,9691	Others	
6521	Sildenafil citrate tablet II	2002	•																			0,9541	Others	
6522	Sildenafil citrate tablet III	2002	•																			0,9673	Others	
6523	Sildenafil citrate tablet IV	2002	•																			0,9694	Others	
6524	Sildenafil citrate tablet V	2002	•																			0,9669	Others	
6525 ¹⁾	Sildenafil citrate tablet VI	2002	•																			0,9500	Others	
A		2002																						Others
B		2002																						Others
6526 ¹⁾	Sildenafil citrate tablet VII	2002	•																			0,9614	Others	
A		2002																						Others
B		2002																						Others
6527	Sildenafil citrate tablet VIII	2002	•																			0,9690	Others	
6528	Sildenafil citrate tablet IX	2002	•																			0,9684	Others	
Samples 6520 - 6528 are obtained from the same batch as sample 6398																								
6529	Levitra 50	2002	43																			0,9155	Non-prof. imitation	
6531	VGR 50	2002							12													0,8035	Fraudulent counterfeit	
6532 ²⁾	Viagra	2002																				0,9326	Prof. counterfeit	
A		2002	50																					Prof. counterfeit
B		2002	53																					Prof. counterfeit
6533	VGR	2002	36																			0,9389	Non-prof. counterfeit	
6534	VGR	2002	37																			0,9392	Non-prof. counterfeit	
6611	Caverta 100	2002	97																			0,9644	Prof. imitation	
6612	Viagra 100	2002	94																			0,8917	Prof. counterfeit	
6619 ³⁾	Viagra 100	2002																				0,9141	Prof. counterfeit	
A		2002	93																					Prof. counterfeit
B		2002	94																					Prof. counterfeit
C		2002	97																					Prof. counterfeit
D		2002	97																					Prof. counterfeit
E		2002	103																					Prof. counterfeit
6620	Viagra 50 mg	2002	49																			0,9327	Prof. counterfeit	
6621	Viagra 50	2002	50																			0,9429	Others	
6622	Viagra 50	2002	50																			0,9444	Prof. counterfeit	
6623	Viagra 100	2002	68																			0,6025	Non-prof. counterfeit	
6624	Oblong spotted tablet	2002	42																			0,9140	Non-prof. imitation	
6625	Blue diamond 100	2002	74																			0,9676	Non-prof. imitation	
6626	Viagra 50	2002	51																			0,9365	Others	
6627	Viagra 50	2002	50																			0,9415	Others	
6628	Viagra 50	2002	51																			0,9372	Others	
6629	Viagra 50	2002	51																			0,9369	Others	
6630	Viagra 50	2002	53																			0,9372	Others	
6640	Blue round tablet	2002	48																			0,9307	Non-prof. imitation	
6649	Viagra half tablet	2002	20								64											0,9600	Mixed imitation	

Sample number	Product name	Year of analysis	Active substance (mg/dosage unit)														Appearance	NIR	Classification				
			Sildenafil	Homosildenafil	Hydroxyhomosildenafil	Acetildenafil	Tadalafil	Vardenafil	Yohimbine	GABA	(Dex)Amphetamine	Caffeine	Clemetine citrate	Dipyrrone	Quinine	L-arginine				Fluoxetine	Indigotine	Chloramphenicol	Others
6650	Sigra 100 mg	2002	77																		diamond-shaped, blue	0,9734	Others
6663	SIGRA number 1	2002	n.d.				7	n.d.	21												hexagonal, blue; SIGRA/SIGRA; brown core	not analysed	Fraudulent imitation
6664	SIGRA number 9	2002	n.d.				7	n.d.	21												hexagonal, blue; SIGRA/SIGRA; brown core	not analysed	Fraudulent imitation
6665	SIGRA number 10	2002	n.d.				7	n.d.	21												hexagonal, blue; SIGRA/SIGRA; brown core	not analysed	Fraudulent imitation
6666	SIGRA number 14	2002	n.d.				7	n.d.	21												hexagonal, blue; SIGRA/SIGRA; brown core	not analysed	Fraudulent imitation
6667	SIGRA number 15	2002	15				n.d.	n.d.	• 27												hexagonal, blue; SIGRA/SIGRA; brown core	not analysed	Mixed imitation
6668	SIGRA number 7	2002	16				n.d.	n.d.	• 26												hexagonal, blue; RX/STA-MINA; brown core	not analysed	Mixed imitation
6669	SIGRA number 7 open	2002	16				n.d.	n.d.	• 22												hexagonal, blue; RX/STA-MINA; brown core	not analysed	Mixed imitation
6670	SIGRA	2002	17				n.d.	n.d.	• 21												hexagonal, blue; RX/STA-MINA; brown core	not analysed	Mixed imitation
6671 ¹⁾	Viagra 50 mg	2002	55																		diamond-shaped, dark blue; Pfizer/VGR 50; white core	0,9378	Prof. counterfeit
A		2002	49																		diamond-shaped, light blue; Pfizer/VGR 50; white core	0,9438	Prof. counterfeit
6692	Viagra Australia Counterfeit	2002																			diamond-shaped, blue; Pfizer/VGR 100	0,9197	Others
6693	Viagra Dutch Counterfeit	2002																			diamond-shaped, blue; Pfizer/VGR 100	0,8851	Others
6694	Viagra	2002	100																		diamond-shaped, blue; Pfizer/VGR 100; white core	0,9166	Prof. counterfeit
6695	Orga-sum	2002	48																		diamond-shaped, light blue; R/50; white core	0,9881	Prof. imitation
6696	Viagra 50mg	2002	49																		diamond-shaped, light blue; Pfizer/VGR 50; white core	0,9371	Prof. counterfeit
6697	Viagra 100mg	2002	98																		diamond-shaped, light blue; Pfizer/VGR 100; white core	0,9165	Prof. counterfeit
6702	Stamina-Rx	2002	n.d.				8	n.d.	25												hexagonal, light blue; RX/STAMINA; brown core	not analysed	Fraudulent imitation
6708	Viagra 100 mg	2002	96																		oval, blue; GSC/GSC 100; with score	0,9522	Prof. imitation
6712	Sigra pallet 1	2002	n.d.				7	n.d.	21												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6713	Sigra pallet 2	2002	n.d.				7	n.d.	22												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6714	Sigra pallet 3	2002	n.d.				7	n.d.	21												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6715	Sigra pallet 4	2002	n.d.				7	n.d.	22												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6716	Sigra pallet 5	2002	n.d.				7	n.d.	22												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6717	Sigra pallet 6	2002	n.d.				7	n.d.	21												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6718	Sigra pallet 7	2002	n.d.				7	n.d.	21												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6719	Sigra pallet 8	2002	n.d.				7	n.d.	21												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6720	Sigra pallet 9	2002	n.d.				7	n.d.	22												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6721	Sigra pallet 10	2002	n.d.				7	n.d.	22												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6722	Sigra pallet 11	2002	n.d.				7	n.d.	22												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6723	Sigra pallet 12	2002	n.d.				7	n.d.	22												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6724	Sigra pallet 13	2002	n.d.				7	n.d.	22												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6725	Sigra pallet 14	2002	n.d.				7	n.d.	22												hexagonal, blue; SIGRA; brown core	not analysed	Fraudulent imitation
6726	Viagra	2002	49																		diamond-shaped, light blue; Pfizer/VGR 50	0,9992	Genuine
6742	Edegra 50	2002	48																		round, blue; no imprint; score on one side	0,9288	Prof. imitation
6746	Viagra	2003	n.d.																		diamond-shaped, blue; Pfizer/VGR 50	0,6746	Fraudulent counterfeit
6747	Viagra	2003	n.d.																		diamond-shaped, blue; Pfizer/VGR 50	0,7262	Fraudulent counterfeit
6748	Viagra	2003	n.d.																		diamond-shaped, blue; Pfizer/VGR 50	0,6843	Fraudulent counterfeit
6749	Viagra	2003	n.d.																		diamond-shaped, blue; Pfizer/VGR 50	0,7241	Fraudulent counterfeit
6750	Viagra	2003	n.d.																		diamond-shaped, blue; Pfizer/VGR 50	0,7006	Fraudulent counterfeit
6751	Viagra	2003	n.d.																		diamond-shaped, blue; Pfizer/VGR 50	0,6769	Fraudulent counterfeit
6752	Viagra	2003	n.d.																		diamond-shaped, blue; Pfizer/VGR 50	0,6824	Fraudulent counterfeit
6762	Erexer	2003	51																		diamond-shaped, red; X/50	0,9912	Prof. imitation
6753	Viagra	2003																			diamond-shaped, blue; Pfizer/VGR 100	0,8193	Others
6754	Viagra	2003																			diamond-shaped, blue; Pfizer/VGR 100	0,8102	Others
6755	Viagra	2003	n.d.																		diamond-shaped, blue; Pfizer/VGR 100	0,8876	Fraudulent counterfeit
6756	Viagra	2003	n.d.																		diamond-shaped, green blue; Pfizer/VGR 100	0,8073	Fraudulent imitation

Sample number	Product name	Year of analysis	Active substance (mg/dosage unit)														Appearance	NIR	Classification				
			Sildenafil	Homosildenafil	Hydroxyhomosildenafil	Acetildenafil	Tadalafil	Vardenafil	Yohimbine	GABA	(Dex)Amphetamine	Caffeine	Clemetine citrate	Dipyrrone	Quinine	L-arginine				Fluoxetine	Indigotine	Chloramphenicol	Others
6767	Viagra 100 mg	2003	99																	diamond-shaped, blue; Pfizer/VGR 100	0,9498	Prof. counterfeit	
6787	Viagra 100 mg	2003																		diamond-shaped, blue; Pfizer/VGR 100; white core	0,8930	Others	
6788	Viagra 50	2003	n.d.																	diamond-shaped, blue; Pfizer/VGR 50; with coating	0,6968	Fraudulent counterfeit	
6789	Viagra 50	2003	n.d.																	diamond-shaped, blue; Pfizer/VGR 50; with coating	0,6999	Fraudulent counterfeit	
6790	Viagra 50	2003	n.d.																	diamond-shaped, blue; Pfizer/VGR 50; with coating	0,6830	Fraudulent counterfeit	
6799	Silagra 100	2003	99																	oval, blue; no imprint; white core; score on one side	0,9509	Non-prof. imitation	
6807	Libido forte	2003	63																	light blue green, opaque capsule with beige spotted powder	not analysed	Non-prof. imitation	
6816	Viagra 100 mg	2003	n.d.																	diamond-shaped, blue; Pfizer/VGR 100	0,7004	Fraudulent counterfeit	
6817	Viagra 100 mg	2003	65																	diamond-shaped, blue; Pfizer/VGR 100	0,8916	Non-prof. counterfeit	
6820	Sigra	2003	16																	hexagonal, light blue; SIGRA	not analysed	Mixed imitation	
6821	Sigra	2003	16																	hexagonal, light blue; SIGRA	not analysed	Mixed imitation	
6822	Sigra	2003	n.d.					7	n.d.											hexagonal, light blue; SIGRA/SIGRA	not analysed	Fraudulent imitation	
6823	Sigra	2003	n.d.					7	n.d.											hexagonal, light blue; SIGRA/SIGRA	not analysed	Fraudulent imitation	
6845	Sildenafil citrate	2003	99																	hexagonal, blue; OMNI-GEN; score on one side	0,9460	Non-prof. imitation	
6858	Sigra	2003	•						17	16										broken	not analysed	Mixed imitation	
6859	Blue coated tablet	2003	14							•	7									oval, blue; no imprint; with coating	not analysed	Mixed imitation	
6860	Sigra	2003	16							•	7									broken	not analysed	Mixed imitation	
6861	Blue powder	2003	n.d.							n.d.	n.d.									bag blue powder	not applicable 3)	Placebo imitation	
6862	Uncoated tablets	2003	14							•	7									round, brown with blue spots; uncoated	not analysed	Mixed imitation	
6863	VGR 100	2003	89																	diamond-shaped, blue; Pfizer/VGR 100	0,5987	Non-prof. counterfeit	
6893	Julang	2003	n.d.	142				n.d.	n.d.											• oval, light yellow; Chinese characters/J.L.	0,9079	Analogue	
6935	Julang	2003	n.d.	•				n.d.	n.d.											• oval, light yellow; Chinese characters/J.L.	0,9152	Analogue	
Samples 6893 and 6935 are considered to be identical																							
6894	Viagra 100 mg	2003	99					n.d.	n.d.											diamond-shaped, blue; Pfizer/VGR 100	0,9422	Prof. counterfeit	
6904	Vigrex	2003	97																	diamond-shaped, blue; VGX/100	0,9405	Prof. imitation	
6916	VGR 50	2003	49																	diamond-shaped, blue; Pfizer/VGR 50	0,9402	Prof. counterfeit	
6917	Round blue tablet	2003	49																	round, blue; no imprint; score on one side	0,9144	Non-prof. imitation	
6918	VGR 50	2003	49																	diamond-shaped, blue; Pfizer/VGR 50	0,9429	Prof. counterfeit	
6919	VGR100	2003	88																	diamond-shaped, blue; Pfizer/VGR 100	0,9298	Non-prof. counterfeit	
6920	Pink VGR50	2003	n.d.							•										diamond-shaped, pink; Pfizer/VGR 50; with coating	0,8133	Fraudulent imitation	
6921	VGR50	2003	50																	diamond-shaped, blue; Pfizer/VGR 50	0,9416	Prof. counterfeit	
6922	VGR100	2003	88																	diamond-shaped, blue; Pfizer/VGR 100	0,9146	Non-prof. counterfeit	
6923	VGR100	2003	87																	diamond-shaped, blue; Pfizer/VGR 100	0,9193	Non-prof. counterfeit	
6924	VGR100	2003	99																	diamond-shaped, blue; Pfizer/VGR 100	0,9397	Prof. counterfeit	
6925	VGR50	2003	47																	diamond-shaped, blue; Pfizer/VGR 50	0,9384	Prof. counterfeit	
6926 ³⁾	VGR100	2003	92																	diamond-shaped, blue; Pfizer/VGR 100	0,9232	Prof. counterfeit	
A		2003	85																			Non-prof. counterfeit	
B		2003																					
6927	Pink tablet	2003	n.d.							•										diamond-shaped, pink; Pfizer/VGR 50	0,8135	Fraudulent imitation	
6928	Round blue tablet	2003	50																	round, blue; score on one side	0,9156	Non-prof. imitation	
6929	VGR50	2003	49																	diamond-shaped, blue; Pfizer/VGR 50	0,9335	Prof. counterfeit	
6930	VGR100	2003	93																	diamond-shaped, blue; Pfizer/VGR 100	0,9155	Prof. counterfeit	
6931	Seki	2003	29																	orange capsule, sandy coloured powder with yellow particles	not analysed	Mixed imitation	

Sample number	Product name	Year of analysis	Active substance (mg/dosage unit)																Appearance	NIR	Classification	
			Sildenafil	Homosildenafil	Hydroxyhomosildenafil	Acetildenafil	Tadalafil	Vardenafil	Yohimbine	GABA	(Dex)Amphetamine	Caffeine	Clemetine citrate	Dipyrrone	Quinine	L-arginine	Fluoxetine	Indigotine				Chloramphenicol
6932	Unknown	2003	33																	red brown capsule, sandy coloured powder with yellow and white particles	not analysed	Mixed imitation
6933	Sigra tablet	2003	16																	hexagonal, blue; RX/STA MINA	not analysed	Mixed imitation
6934	Sigra tablet	2003	16																	hexagonal, blue; RX/STA MINA	not analysed	Mixed imitation
6940	Viagra	2003																		diamond-shaped, blue; Pfizer/VGR 50; white core	0,8915	Others
6941	Viagra	2003																		diamond-shaped, blue; Pfizer/VGR 50; white core	0,8970	Others
6942	Viagra	2003																		diamond-shaped, blue; Pfizer/VGR 50; white core	0,8871	Others
6943	Viagra	2003																		diamond-shaped, blue; Pfizer/VGR 50	0,8899	Others
6944	Viagra	2003																		diamond-shaped, blue; Pfizer/VGR 100	0,8992	Others
6999	Viagra 50 mg	2003	50																	diamond-shaped, blue; Pfizer/VGR 50	0,9418	Prof. counterfeit
7000	Viagra 100 mg	2003	92																	diamond-shaped, blue; Pfizer/VGR 100	0,9194	Prof. counterfeit
7001	Viagra 100 mg	2003	91																	diamond-shaped, blue; Pfizer/VGR 100	0,9116	Prof. counterfeit
7002	Kamagra	2003	98																	diamond-shaped, blue; symbol/KGR 100	0,9883	Prof. imitation
7003	Edegra 50 mg	2003	49																	round, blue; score on one side	0,9135	Prof. imitation
7005	Viagra 100 mg	2003	87																	diamond-shaped, blue; Pfizer/VGR 100	0,8990	Non-prof. counterfeit
7006	Viagra 50 mg	2003	49																	diamond-shaped, blue; Pfizer/VGR 50	0,9329	Prof. counterfeit
7007	Edegra	2003	48																	round, blue; score on one side	0,9194	Non-prof. imitation
7008	Viagra 100 mg	2003	93																	diamond-shaped, blue; Pfizer/VGR 100	0,9291	Prof. counterfeit
7009	Viagra 100 mg	2003	85																	diamond-shaped, blue; Pfizer/VGR 100	0,9091	Non-prof. counterfeit
7039	Salmon pink capsules	2003	67					n.d.												transparent capsules with salmon pink powder	not analysed	Non-prof. imitation
7043	Yellow capsules (5 bags)	2003	n.d.					22												transparent capsules with yellow powder	not analysed	Fraudulent imitation
7050	Orange capsules (3 bags)	2003	68					n.d.												transparent capsules with orange powder	not analysed	Non-prof. imitation
7051	Dark grey capsule (23 bags)	2003	96					n.d.												transparent capsules with dark gray powder	not analysed	Non-prof. imitation
7052	Afrodisiac, 60 mg, girls	2003	*					n.d.												transparent capsules with salmon pink powder with white particles	not analysed	Non-prof. imitation
7053	Yellow capsules (13 stuks)	2003	n.d.					22												transparent capsules with yellow powder	not analysed	Fraudulent imitation
7054	Grey capsule (1 stuk)	2003	100					n.d.												transparent capsules with gray powder	not analysed	Non-prof. imitation
7055	Yohimbe plus, pale grey capsules	2003	28					12												transparent capsules with light gray powder	not analysed	Mixed imitation
7056	Yohimbe plus, 1 salmon pink capsule	2003	73					n.d.												transparent capsules with salmon pink powder	not analysed	Non-prof. imitation
7057	Pale grey capsules (2 bags)	2003	56					n.d.												transparent capsules with light gray powder	not analysed	Non-prof. imitation
7058	Gray green capsules (3 bags)	2003	80					n.d.												transparent capsules with gray green powder	not analysed	Non-prof. imitation
7117	Fiagra 50 mg	2003	46																	diamond-shaped, blue; Fiagra/FGR 50	0,9188	Prof. imitation
7118	Fiagra 100 mg	2003	90																	diamond-shaped, blue; Fiagra/FGR 100; with coating	0,9224	Prof. imitation
7123	Vigrex DS	2003	80																	diamond-shaped, blue; VGX/100; with coating	0,9582	Non-prof. imitation
7124	Sildenafil Citrate	2003	82																	diamond-shaped, blue; ZGV/100; with coating	0,9591	Non-prof. imitation
7125	Sigra	2003	n.d.					8												hexagonal, blue; SIGRA/SIGRA	0,8508	Fraudulent imitation
7126	Sigra	2003	n.d.					9												hexagonal, blue; SIGRA/SIGRA	0,6915	Fraudulent imitation
7131	Libido 7	2003	n.d.					n.d.												oblong, blue; no imprint	not analysed	Fraudulent imitation
7132	Love drops	2003	n.d.					n.d.												brown, turbid liquid; odourless	not analysed	Placebo imitation
7133	Hot sex girl	2003	n.d.					n.d.												brown, clear liquid; odourless	not analysed	Placebo imitation
7134	4 Pleasure	2003	n.d.					n.d.												gray capsule with brown powder	not analysed	Placebo imitation
7135	VP-Rex	2003	n.d.					n.d.												transparent capsule with beige powder	not analysed	Fraudulent imitation
7136	Vigorin for men	2003	n.d.					n.d.												red and white capsule with brown beige powder	not analysed	Fraudulent imitation
7137	Penis-Temposex classic	2003	n.d.					n.d.												red and brown capsule with brown paste	not analysed	Placebo imitation
7138	Rush	2003	n.d.					n.d.												light yellow, clear liquid; odourless	not analysed	Placebo imitation
7139	Libido power	2003	n.d.					n.d.												oblong, blue	not analysed	Fraudulent imitation
7140	Libido power	2003	n.d.					n.d.												oblong, blue; no imprint	not analysed	Fraudulent imitation
7141	Libido Forte	2003	*					n.d.												blue capsule with brown powder	not analysed	Non-prof. imitation
7142	Ecstatic	2003	n.d.					n.d.												oblong, beige spotted; no imprint	not analysed	Fraudulent imitation
7143	Yohimbe Passion	2003	n.d.					n.d.												oblong, brown; no imprint	not analysed	Fraudulent imitation
7144	Yoccoine	2003	n.d.					n.d.												brown, clear liquid; odourless	not analysed	Placebo imitation
7145	Erexer	2003	n.d.					n.d.												diamond-shaped, blue	not analysed	Others
7146	Lady plus	2003	n.d.					n.d.												yellow, turbid liquid; odourless	not analysed	Placebo imitation
7147	Potency total	2003	n.d.					n.d.												red and brown capsule with brown paste	not analysed	Placebo imitation

Sample number	Product name	Year of analysis	Active substance (mg/dosage unit)														Appearance	NIR	Classification					
			Sildenafil	Homosildenafil	Hydroxyhomosildenafil	Acetildenafil	Tadalafil	Vardenafil	Yohimbine	GABA	(Dex)Amphetamine	Caffeine	Clemetine citrate	Dipyrrone	Quinine	L-arginine				Fluoxetine	Indigotine	Chloramphenicol	Others	
7148	Venicon	2003	n.d.																		diamond-shaped, blue; no imprint	not analysed	Fraudulent imitation	
7149	Penis kraft dragees	2003	n.d.																		round, orange; no imprint	not analysed	Placebo imitation	
7150	Vigorin for women	2003	n.d.																		blue and white capsule with brown powder	not analysed	Placebo imitation	
7151	Spanish fly	2003	n.d.																		light brown, clear liquid; odourless	not analysed	Fraudulent imitation	
7152	Extase	2003	n.d.																		light yellow, clear liquid; odourless	not analysed	Fraudulent imitation	
7170	Stamina-Rx	2003	n.d.																		hexagonal, blue; R/Stamina	not analysed	Fraudulent imitation	
7178	Viagra 100 mg	2003	70																		diamond-shaped, blue; Pfizer/VGR 100; with coating	0,9797	Non-prof. counterfeit	
7179	Viagra 100 mg	2003	65																		diamond-shaped, blue; Pfizer/VGR 100; with coating	0,9776	Non-prof. counterfeit	
7198	Viage1	2003	n.d.																		light pink, clear transparent gel; light stimulating sweet odour	not analysed	Fraudulent imitation	
7215	Pink tablet	2003	n.d.																		diamond-shaped, pink; Pfizer/VGR 50	0,7751	Fraudulent imitation	
7216 ²⁾	Blue tablet	2003																			diamond-shaped, blue; no imprint	0,9635		
A		2003	50																				Non-prof. imitation	
B		2003	40																				Non-prof. imitation	
7217	Viagra	2003	24																		diamond-shaped, blue; Pfizer/VGR 50	0,9292	Non-prof. counterfeit	
7218	Viagra	2003	23																		diamond-shaped, blue; Pfizer/VGR 50; white core	0,9189	Non-prof. counterfeit	
7219	Viagra	2003	23																		diamond-shaped, blue; Pfizer/VGR 50	0,9144	Non-prof. counterfeit	
7220	Venicon	2003	n.d.																		diamond-shaped, light blue/green; no imprint	0,9413	Fraudulent imitation	
7221	Vantaggio	2003	n.d.																		blue capsule with beige powder	not applicable 3)	Fraudulent imitation	
7222	Libido Forte	2003	62																		light blue green capsules	not applicable 3)	Non-prof. imitation	
7223	Kamagra	2003	99																		diamond-shaped, blue; symbol/KGR 100	0,9933	Prof. imitation	
7224	Venicon	2003	n.d.																		diamond-shaped, orange-brown; no imprint	0,9566	Fraudulent imitation	
7225	Viagra 50mg	2003	48																		diamond-shaped, blue; Pfizer/VGR 50	0,9584	Prof. counterfeit	
7226	Vantaggio	2003	n.d.																		blue capsules	not applicable 3)	Fraudulent imitation	
7227	Erecta 100	2003	43																		diamond-shaped, blue; YP/ERT 100	0,9774	Non-prof. imitation	
7228	Penis XL	2003	n.d.																		oval, brown with white spots; no imprint	0,9029	Placebo imitation	
7229	Viagra	2003	23																		diamond-shaped, blue; Pfizer/VGR 50	0,9340	Non-prof. counterfeit	
7230	Viagra 50mg	2003	50																		diamond-shaped, light blue; Pfizer/VGR 50	0,9816	Prof. counterfeit	
7235	Libido Forte Herbal Supply	2003					60														blue capsule with gray purple powder with white lumps	not applicable 3)	Analogue	
7240	Unknown	2003																			diamond-shaped, blue; 100 on one side	0,9645	Others	
7241	Viagra 100	2003																			diamond-shaped, blue; Pfizer/VGR 100	0,9023	Others	
7244	Caverta 50	2004	•																		triangular, red; 50	0,9891	Others	
7245	Viagra 50 mg	2004	18																		diamond-shaped, blue; Pfizer/VGR 50; white core	0,8914	Non-prof. counterfeit	
7246	Kamagra 100	2004	•																				0,9940	Others
7269	Viagra 50 mg	2004	24																		diamond-shaped, blue; Pfizer/VGR 50; white core	not analysed	Non-prof. counterfeit	
7270	Kamagra	2004	103																		diamond-shaped, blue; symbol/KGR 100; white core	not analysed	Prof. imitation	
7271	Viagra 50 mg	2004	23																		diamond-shaped, blue; Pfizer/VGR 50; white core	not analysed	Non-prof. counterfeit	
7272	Kamagra	2004	104																		diamond-shaped, blue; symbol/KGR 100; white core	not analysed	Prof. imitation	
7273	Viagra (from the house)	2004	51																		diamond-shaped, blue; Pfizer/VGR 50; white core	not analysed	Others	
7274	Viagra (from the car, envelope A)	2004	49																		diamond-shaped, blue; Pfizer/VGR 50; white core	not analysed	Others	
7275	Viagra (from the car, envelope B)	2004	51																		diamond-shaped, blue; Pfizer/VGR 50; white core	not analysed	Others	
7276	Viagra (from the car, envelope C)	2004	52																		diamond-shaped, blue; Pfizer/VGR 50; white core	not analysed	Others	
7292	EreForte	2004	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.													transparent capsules with beige powder	not analysed	Placebo imitation	
7293	Satibo	2004	40																		capsules	not analysed	Analogue	
7295	Aqua-T	2004	T																		diamond-shaped, blue; no imprint; uncoated	0,3774	Placebo imitation	
7296	Separate tablet, light blue, large	2004	42																		diamond-shaped, light blue; no imprint; uncoated	0,8871	Non-prof. imitation	
7297	Sepearat tablet, cupido	2004	41																		diamond-shaped, light blue; CUPIDO 50; uncoated	0,9341	Non-prof. imitation	
7298	Separate tablet, light blue, large	2004	44																		diamond-shaped, light blue; no imprint; uncoated	0,9309	Non-prof. imitation	
7299	Separate tablet, blue, small	2004	29																		diamond-shaped, blue; no imprint; white core	0,9542	Non-prof. imitation	
7300	Separate tablet, Pfizer VGR100bl	2004	94																		diamond-shaped, blue; Pfizer/VGR 100; white core	0,9606	Prof. counterfeit	

Sample number	Product name	Year of analysis	Active substance (mg/dosage unit)														Appearance	NIR	Classification							
			Sildenafil	Homosildenafil	Hydroxyhomosildenafil	Acetildenafil	Tadalafil	Vardenafil	Yohimbine	GABA	(Dex)Amphetamine	Caffeine	Clomifene citrate	Dipyrrone	Quinine	L-arginine				Fluoxetine	Indigotine	Chloramphenicol	Others			
7301	Separate tablet, blue, large	2004	45																		diamond-shaped, light blue; no imprint; uncoated	0,8941	Non-prof. imitation			
7302	Separate tablet, Pfizer VGR 50 bl	2004	38																		diamond-shaped, light blue; Pfizer/VGR 50; uncoated	0,9447	Non-prof. counterfeit			
7303	Separate tablet, Pfizer VGR 50 white	2004	34																		diamond-shaped, white; Pfizer/VGR 50; uncoated	0,9338	Non-prof. imitation			
7304	Separate tablet, Cupido	2004	42																		diamond-shaped, light blue; CUPIDO 50; uncoated	0,9348	Non-prof. imitation			
7305 ²⁾	Tablet, Viagra 100 mg	2004																				0,9452				
A		2004	91																							
B		2004	96																							
7308	Tablet, Viagra 50 mg	2004	50																			0,9510	Prof. counterfeit			
7309 ¹⁾	Tablet, Viagra 50 mg	2004	49																				Prof. counterfeit			
A		2004																				0,9579	Prof. counterfeit			
B		2004																				0,9521	Prof. counterfeit			
7310	Tablet, Viagra	2004	50																			0,9575	Prof. counterfeit			
7311	Aqua-T	2004	T																			0,3786	Placebo imitation			
7312	Fiagra 100 mg	2004	107																			0,9330	Prof. counterfeit			
7313	Aqua-T	2004	T																			0,3793	Placebo imitation			
7314	Fiagra	2004	109																			0,9394	Prof. imitation			
7315	Viagra 50 mg	2004	49																			0,9627	Prof. counterfeit			
7322	Libido Power	2004	n.d.					n.d.	n.d.	•													not analysed	Others		
7323	Sigra plus	2004						0.2															not analysed	Fraudulent imitation		
7324	Libido +	2004	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.														not analysed	Placebo imitation		
7325	Libidift	2004				62																	not analysed	Analogue		
7326	Libidift	2004				64																	not analysed	Analogue		
7327	Kamagra oral jelly	2004	101																				not analysed	Non-prof. imitation		
7328	V-Conqueror	2004	•																				not analysed	Others		
7337	Blue tablet	2004	47																				not analysed	Prof. imitation		
7338	Viagra 100 mg	2004	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.														0.4	•	diamond-shaped, blue; Pfizer/VGR 100; white core; with coating	0,6361	Fraudulent counterfeit
7354	VGR50	2004	16																				0,9428	Non-prof. counterfeit		
7355	VGR50	2004	17																				0,9368	Non-prof. counterfeit		
7356	VGR50	2004	17																				0,9353	Non-prof. counterfeit		
7357 ²⁾	VGR50	2004																					0,9497			
A		2004	15																							
B		2004	17																							
7358	VGR50	2004	17																				0,9435	Non-prof. counterfeit		
7359	VGR50	2004	16																				0,9391	Non-prof. counterfeit		
7371	Blue powder	2004	10.2 %																				not applicable 3)	Fraudulent imitation		
7372	Blue powder	2004	<0.05 %																				not applicable 3)	Fraudulent imitation		
7373	Blue powder	2004	12.7 %																				not applicable 3)	Mixed imitation		
7374	Blue powder	2004	<0.05 %																				not applicable 3)	Fraudulent imitation		
7375	Blue powder	2004	<0.05 %																				not applicable 3)	Fraudulent imitation		
7385	Viacaps	2004			33																		not analysed	Analogue		
7433	Powergra 100	2004	94																				not analysed	Prof. imitation		
7434	Viagra plus 100 mg	2004	93																				not analysed	Prof. counterfeit		
7435	Lady viagra 100 mg	2004								30													not analysed	Fraudulent imitation		
7436	Herbal drink (lemon flavour)	2004				4 mg/can																	not analysed	Analogue		
7437	Herbal drink (cassis flavour)	2004				7 mg/can																	not analysed	Analogue		
7445	Libidift	2004				71																	not analysed	Analogue		
7450	Libidift	2004				57																	not analysed	Analogue		
7451	Libidift	2004				53																	not analysed	Analogue		

Sample number	Product name	Year of analysis	Active substance (mg/dosage unit)														Appearance	NIR	Classification				
			Sildenafil	Homosildenafil	Hydroxyhomosildenafil	Acetildenafil	Tadalafil	Vardenafil	Yohimbine	GABA	(Dex)Amphetamine	Caffeine	Clomifene citrate	Dipyrrone	Quinine	L-arginine				Fluoxetine	Indigotine	Chloramphenicol	Others
7452	Libidift	2004				67															blue and white capsules with brown powder	not analysed	Analogue
7453	Libidift	2004				70															blue and white capsules with beige powder	not analysed	Analogue
7454	powder A	2004				256 mg/g															brown powder in bag	not applicable 3)	Analogue
7455	Capsule	2004				53															blue and white capsules with brown powder	not analysed	Analogue
7456	powder B	2004				262 mg/g															brown powder in bag	not applicable 3)	Analogue
7457	Capsule	2004				88															blue and white capsules with brown powder	not analysed	Analogue
7458	Capsule	2004				76															blue and white capsules with brown powder	not analysed	Analogue
7459	powder D	2004				311 mg/g															brown powder in bag	not applicable 3)	Analogue
7460	Capsule	2004				86															blue and white capsules with brown powder	not analysed	Analogue
7461	Libidift	2004				75															blue and white capsules with brown powder	not analysed	Analogue
7462	Libidift	2004				76															blue and white capsules with beige powder	not analysed	Analogue
7463	Libidift	2004				96															blue and white capsules with brown powder	not analysed	Analogue
7464	Libidift	2004				81															blue and white capsules with brown powder	not analysed	Analogue
7465	Libidift	2004				81															blue and white capsules with brown powder	not analysed	Analogue
7481	Rhiz. Polygonatum, raw	2004				T															dried herb, rootstock	not analysed	Placebo imitation
7482	Rhiz. Polygonatum, fermented	2004				14 mg/g															dried herb, rootstock	not analysed	Placebo imitation
7483	Rhiz. Polygonatum, concentrate	2004				500 mg/g															light brown powder	not applicable 3)	Analogue
7487	Flagra	2004	112																		diamond-shaped, blue; Flagra/FGR 100; with coating	not analysed	Non-prof. imitation
7488	Aqua-T	2004	T																		diamond-shaped, dark blue spotted; no imprint; uncoated	not analysed	Placebo imitation
7489	VGR 50	2004	50																		diamond-shaped, blue; Pfizer/VGR 50; with coating	not analysed	Others
7495	Miamora	2004	T																		light blue capsule with brown with white granules; MIAmora NX	not analysed	Placebo imitation
7508	Kamagra 100 mg (pineapple flavour)	2004	103																		gel	not analysed	Prof. imitation
7509	Kamagra 100 mg (orange flavour)	2004	98																		gel	not analysed	Prof. imitation
7526	Stamina-Rx	2004	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	3													not analysed	Others
7539	Kamagra 100 mg tablets	2004	*																			not analysed	Others
7540	Kamagra oral jelly (pineapple flavour)	2004	*																		gel	not analysed	Others
7558	Capsules blue and white	2004	47	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												blue and white capsule with powdered Viagra	0,9993	Non-prof. imitation
7562	Viagra	2004	45	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												diamond-shaped, blue; Pfizer/VGR 100	0,9164	Non-prof. counterfeit
7653	Blue tablet (viagra 100 mg)	2004																				0,9950	Others
7662	Penegra 100	2004	95	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												diamond-shaped, pink; Z/100; white core	0,9509	Prof. imitation
7663	Zenegra-100	2004	93	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												diamond-shaped, blue; no imprint; white core	0,9748	Prof. imitation
7664	Edegra 50	2004	45	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												round, pink; no imprint; white core; score on one side	0,9290	Prof. imitation
7665	Caverta 100	2004	44	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												triangular, red; 50; white core	0,9869	Prof. imitation
7666	Caverta 100	2004	91	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												triangular, red; 100; white core	0,9889	Prof. imitation
7667	Vega 50	2004	44	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												diamond-shaped, blue; Vega/50; white core	0,9786	Prof. imitation
7668	Vega 50	2004	48	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												diamond-shaped, blue; Vega/50; white core	0,9767	Prof. imitation
7669	Kamagra 100	2004	97	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												diamond-shaped, blue; symbol/KGR 100; white core	0,9921	Prof. imitation
7670	Silagra 100	2004	94	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												oval, light blue; no imprint; white core; score on one side	0,9450	Prof. imitation
7671	Kalmagra 100	2004	96	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												diamond-shaped, blue; 100; white core	0,9743	Prof. imitation
7672	Target 50	2004	37	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												diamond-shaped, blue spotted; 50; white core	0,9509	Nonprof. Imitation
7674	Sildenafil ?	2004	52	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												light yellow and dark red capsule with white powder	0,6693	Nonprof. Imitation
7676	Sildenafil soft tabs 100	2004	86	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												diamond-shaped, pale blue with dark blue spots; 100; uncoated	0,8499	Nonprof. Imitation
7679	Sildenafil citrate	2004																			bulk	not applicable 3)	Others
7700	Jin gang Yi Hao	2004	73	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												diamond-shaped, blue; VAG/VAG; white core	0,9777	Nonprof. Imitation
7701 ²⁾	Viagra 50	2004																			diamond-shaped, blue; Pfizer/VGR 50; white core	0,9984	Prof. counterfeit
A		2004	47	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												blue different from 7701B		Prof. counterfeit
B		2004	45	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												blue different from 7701A		Prof. counterfeit
7702	Erecto-50	2004	47	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												oval, light blue; no imprint; white core; score on one side	0,9540	Prof. imitation
7703	GSC-100 blue band	2004	72	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												oblong, turquoise; GSC 100/GSC (within a diamond); uncoated; score on one side	0,9497	Nonprof. Imitation
7704	GSC-100 black band	2004	68	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												oblong, turquoise; GSC 100/GSC (within a diamond); uncoated; score on one side	0,9493	Nonprof. Imitation
7705	Omnigen	2004	60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.												hexagonal, turquoise; OMNI- GEN; uncoated; score on one side	0,9442	Nonprof. Imitation

Sample number	Product name	Year of analysis	Active substance (mg/dosage unit)															Appearance	NIR	Classification				
			Sildenafil	Homosildenafil	Hydroxyhomosildenafil	Acetildenafil	Tadalafil	Vardenafil	Yohimbine	GABA	(Dex)Amphetamine	Caffeine	Clomifene citrate	Dipyrrone	Quinine	L-arginine	Fluoxetine				Indigotine	Chloramphenicol	Others	
7706	Zwagra 50 mg	2004	24	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.											diamond-shaped, blue; ZWAGRA; white core; score on one side	0,9531	Nonprof. Imitation
7707	Zeagra 100 mg	2004	89	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.											diamond-shaped, dark blue; 100; white core	0,9205	Nonprof. Imitation
7708	Caverta 100	2004	88	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.											triangular, red; 100; white core	0,9859	Nonprof. Imitation
7709	Vega 100	2004	91	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.											diamond-shaped, blue; 100; white core	0,9663	Prof. imitation
7710	Androz-100	2004	64	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.											round, blue; no imprint; white core	0,7134	Nonprof. Imitation
7711	Levitra 50 mg	2004	39	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.											oblong, blue with dark blue spots; no imprint; uncoated	0,9242	Nonprof. Imitation
7712	Vega 50	2004	43	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.											diamond-shaped, blue; Vega/50; white core	0,9758	Nonprof. Imitation

Analytical results of Cialis falsifications

Sample number	Product name	Year of analysis	Active substance (mg/dosage unit)															Appearance	NIR	Classification						
			Sildenafil	Homosildenafil	Hydroxyhomosildenafil	Acetildenafil	Tadalafil	Vardenafil	Yohimbine	GABA	(Dex)Amphetamine	Caffeine	Clomifene citrate	Dipyrrone	Quinine	L-arginine	Fluoxetine				Indigotine	Chloramphenicol	Others			
7004	Cialis 20 mg	2003					20															round, pink; no imprint	0,8149	Prof. imitation		
7510	Cialis 20 mg	2004	6	n.d.	n.d.		4	n.d.	n.d.													almond-shaped oval, beige; C20	0,6993	Mixed counterfeit		
7541	Cialis 20 mg	2004					•																	0,7103	Others	
7650	Cialis 20 mg	2004	7				5																	0,7244	Others	
7651	Cialis 20 mg	2004					19																		0,7137	Others
7652	Cialis 20 mg, Reference tablets	2004					20																		0,9992	Genuine
7680	Cialis	2004	13	n.d.	n.d.	n.d.	9	n.d.	n.d.													almond-shaped, yellow; C 20 at one side; white core almond-shaped, yellow; C 20 at one side; white core	0,9360	Mixed counterfeit		
7673	Apcalis 20	2004	n.d.	n.d.	n.d.	n.d.	18	n.d.	n.d.													almond-shaped, yellow; A 20; white core	0,9516	Prof. imitation		
7675	Tadalafil	2004	n.d.	n.d.	n.d.	n.d.	5	n.d.	n.d.													bright yellow and gray capsule with white powder	0,9675	Nonprof. Imitation		

• present
n.d. not detected
T traces present

- different types of tablets, based on NIR
- different types of tablets, based on differences in appearance
- a validated reference library for powders is not available, therefore NIR measurements are not applicable