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Quality control of drugs sold in Niamey: case of analgesics

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Abstract:
Introduction: In recent decades, the sale of medicines outside the official pharmacy circuit has become widespread in developing countries. Niger and other developing countries, which are heavily dependent on imports, need to set up and maintain an effective product testing program. The aim of this study is to compare the quality of analgesics (paracetamol, aspirin, ibuprofen, diclofenac sodium and tramadol) with reference products of known quality.
Materials and methods: 27 samples of analgesics from ambulant markets and pharmacies were tested, including a visual examination, a labelling check, a mass uniformity test and identification of the active ingredient.
Results: Of the 27 samples analyzed, the identification, visual examination and mass uniformity tests were all compliant. For the labeling test, more than half of the samples were non-compliant. The main non-conformities detected were: absence of manufacturing date (48.14%); absence of expiry date (3.70%); and absence of manufacturer's address (11.11%).
Conclusion: The study showed that, to ensure the health of the population in terms of medicines, our political decision- and policy-makers must become more involved in the fight against the illicit sale of medicines on the one hand, and on the other, ensure that only good-quality medicines are dispensed in approved structures.
Key words: *quality control; illicit market; pharmacy; analgesic; Niger.*

I. INTRODUCTION

The sale of medicines outside of the official pharmacy supply chain has become widespread in developing countries over the last few decades [1].

The informal drug network has grown considerably in Niger since the advent of multi-party politics in 1991 and the lifting of the monopoly of the Office National des Produits Pharmaceutiques et Chimiques in 1997 [2-3]. Despite the existence of a legal framework that specifies the pharmacist's monopoly in the field of medicines, laboratory reagents and medical consumables, the illicit drug distribution system has developed in all the major towns and villages, where real wholesalers have set up shop, branching out into a veritable network of street traders, most often unemployed young people [3].

The highly developed illicit market in Niger is a potential source of public health risks. Today, there are several categories of non-compliant medicines: overdoses, underdoses, counterfeits and degraded products [3-4]. Their frequency, which is difficult to quantify, appears to be increasing, and developing countries are the most affected. A number of factors encourage their circulation: problems of access to medicines, which encourage the emergence of parallel markets; the liberalization of international trade; and the absence of effective legislation at both national and international level to protect the quality of medicines [5-6].

This study is limited to the quality control of analgesics. We chose these drugs because they are at the heart of national pharmaceutical policies initiated by the World Health Organization (WHO), and the class of analgesics for two reasons : their non-compliance has repercussions on public health; they are more often subject to counterfeiting. The aim of this study is to compare the quality of analgesics (paracetamol, aspirin, ibuprofen, diclofenac sodium and tramadol) with reference products of known quality.

II. MATERIALS AND METHODS

2.1. Type of study

This is an analytical and comparative study. It was carried out within the Faculty of Science and Technology of the Abdou Moumouni University in Niamey, from 15/03/2024 to 19/09/2024. It concerns medicines sold on parallel markets and those sold in pharmacies.

2.2. Sampling

The study was carried out on twenty-seven (27) samples of drugs. It focused on analgesics frequently used to treat pain. Drug samples were collected from two sources: pharmacies and street markets.

2.3. Sample size

The study concerned a total of 27 samples and 5 references presented in Table I. The references are the active ingredients of these drugs in their pure state, and serve as positive controls for the tests performed.

Table I: Sample sizes

Trade name and dosage	Pharmacy	Ambulant market	References
Paracetamol 500mg	03	03	01
Aspirin 500mg	03	03	01
Ibuprofen 400mg	03	03	01
Diclofenac sodium 50mg	03	03	01
Tramadol 120mg	00	03	01
Total	12	15	05

2.4. Inclusion criteria

The study included only paracetamol (4'-hydroxyacetanilide or acetaminophen), aspirin (2-acetoxybenzoic acid or acetylsalicylic acid), ibuprofen (p-isobutylhydratropic acid or 4-isobutyl-2-methylphenylethanoic acid), diclofenac sodium ([2-[(2,6-Dichlorophenyl) amino] phenyl] acetate) and Tramadol (2-(dimethylamino) methyl]-1-(3-methoxyphenyl) cyclohexanol), the most commonly sold analgesics.

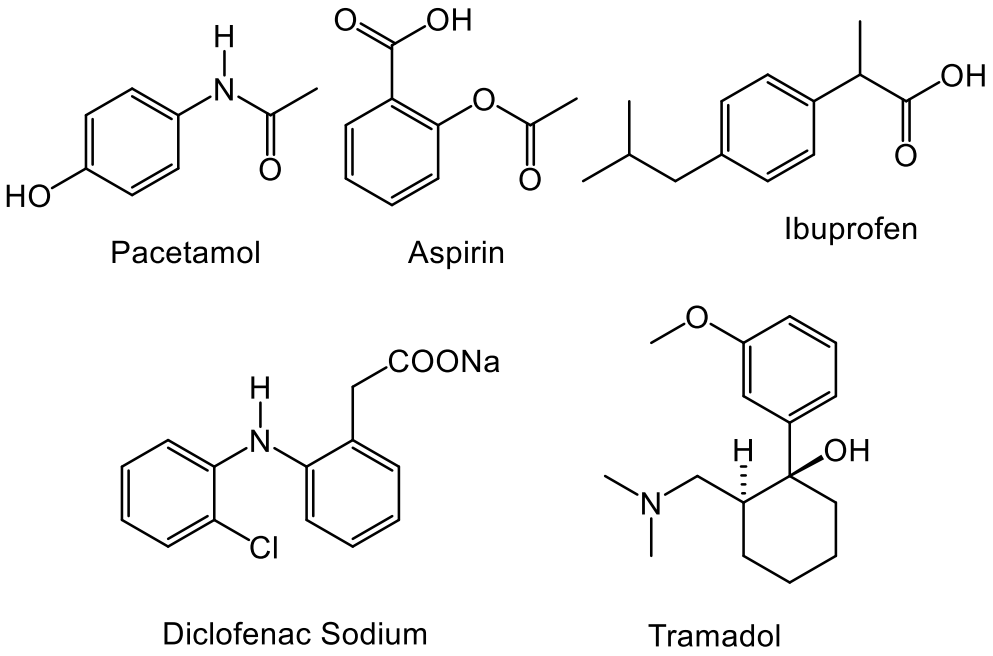

Figure 1 : Chemical structures of analgesics

2.5. Exclusion criteria

Drugs that were not paracetamol, aspirin, ibuprofen, diclofenac sodium or tramadol based, and drugs composed of these with other active ingredients, were excluded from the study.

2.6. Data analysis

For data analysis, Origin6.0 Professional and Visio4.0 Professional software were used.

2.7. Methods of analysis

2.7.1 Visual examination of samples

Visual examination of the tablets or capsules was carried out to check their appearance and color uniformity, first on the surface and then in the mass.

Principle: remove 5 tablets or 5 capsules from the packaging of each sample for visual examination [6-7].

2.7.2 Labeling control

Principle: this involves checking the package label for the product name, active ingredient, batch number, date of manufacture, expiration date and name of the manufacturing laboratory [6-7].

2.7.3 Mass uniformity test

Twenty randomly selected tablets (or capsule contents) are individually weighed and the average of the values obtained is then determined [7].

2.7.4 Identification by thin-layer chromatography (TLC)

To identify the solutions, the principle of thin-layer chromatography was used. The method was carried out in three main stages [8-10] :

- Spot deposit: Deposit a capillary drop of each test solution and reference at 1 cm from the bottom edge of the plate.
- Development: Carefully place in a development chamber, then remove from the development chamber when the migration solvent moves to about 1 cm from the top edge of the plate (development time approx. 30 minutes).
- Detection: Reveal chromatogram after exposure to iodine vapors.

Table II: Preparation of solutions and eluting solvent

Drug	Preparation of test and reference solutions	Eluting solvent
Paracetamol 500 mg	0,1g of paracetamol in 5 mL of ethanol	65 mL chloroform 25 mL acetone 10 mL toluene
Aspirin 500 mg	50 mg of aspirin in 5 mL of methanol	30 mL hexane 30 mL chloroform 15 mL acetone 1 mL acetic acid
Ibuprofen 400 mg	10 mg of Ibuprofen in 1 mL of chloroform	45 mL hexane 15 mL ethyl acetate 3 mL acetic acid
Diclofenac sodium 50 mg	50 mg of diclofenac sodium in 5 mL of methanol.	30 mL hexane 30 mL chloroform 15 mL acetone 0.5 mL acetic acid
Tramadol 120 mg	50 mg of tramadol in 5 mL of methanol.	80 mL toluene 19 mL 2-propanol 1 mL ammoniac

III. RESULTS AND DISCUSSION

3.1 Visual examination of samples

The aspect and color of tablets or capsule contents are shown in Table III.

Table III: Visual examination of samples

Pharmaceutical form	Aspect and color of tablets
Paracetamol	White, scored and marked tablets
Aspirin	White, scored tablets
Diclofenac sodium	Small, red, biconvex tablets
Ibuprofen	Red, biconvex, tablets with sugar coating

Tramadol	Capsule, white crystalline powder

The visual examination (table III) of the pharmaceutical forms in terms of appearance and color of all the samples analyzed for each molecule complies with the rules of Good Manufacturing Practice (GMP). Abnormal labels are due to non-compliance with GMP [11-12].
These results are comparable to those obtained by Ndong Ekorezock in Mali in 2006 on the quality control of injectable oxytetracycline, where out of 86 samples analyzed, sample labeling was found to be non-compliant only for unknown laboratory products [7].

3.2. Labelling control

Out of 27 samples checked, we found :
-13 samples (48.14%) had no date of manufacture;
-3 samples (11.11%) were manufactured by unknown laboratories;
-1 sample (3.70%) had no expiration date.
The same lack of quality was already observed in the study carried out in Niger in 1997 [13], which showed that out of 27 products paid for in the street and analyzed at the quality control laboratory, identification was correct for all 27 products, but,
- 1 product had a different appearance from the reference
- 6 products (22%) showed a lack of mass uniformity
- 6 products (22%) had an abnormally high disintegration time
- 4 batches (14.8%) had a non-compliant dissolution test
- 3 batches (11%) were under-dosed

A study carried out in Niamey in 2004 on the quality control of 2 antimalarial molecules, chloroquine and sulfadoxine/pyrimethamine, showed that out of 75 batches analyzed (50 chloroquine and 25 sulfadoxine/pyrimethamine), 26 batches (34.66%) were non-compliant (52% of sulfadoxine/pyrimethamine batches, 26% of chloroquine batches) [14]. The same study showed that samples from the illicit market (44%) were more non-compliant than those purchased from pharmacies, with a rate of 24%. Six samples did not even contain the active ingredient mentioned.
This problem of poor quality is not confined to Niger. One study looked at some of the most widely used anti-infective drugs (Amoxicillin, Benzylpenicillin, Chloramphenicol, Sulfamethoxazole/Trimethoprim, Tetracycline, Mebendazole, Metronidazole and Quinine) sold on the streets of Cambodia. A total of 144 samples were analyzed, of which 108 were found to be compliant and 36 non-compliant [15].

3.3. Mass uniformity test

Average sample weights are given in Table IV.

Table IV: Average sample weights
MM : Mean mass; ND : Not Determined; M : Market ; P : Pharmacy

	M1	M2	M3	P1	P2	P3
Mean mass of paracetamol 500mg						
MM (mg)	575,6±10,5	572,1±8,3	571,1±5,4	614,0±23,0	570,2±31,0	597,8±10,0
Mean mass of aspirin 500mg						
MM (mg)	571,7±11,3	560,6±4,7	569,0±10,0	580,0±6,7	562,8±4,3	575,5±12,7
Mean mass of ibuprofen 400mg						
MM (mg)	904,3±55,7	663,6±21,4	667,7±21,4	681,1±7,6	718,5±35,6	802,28±8,2
Mean mass of diclofenac sodium 50mg						
MM (mg)	130,7±4,5	130,7±1,7	130,2±2,2	174,9±5	175,9±2,2	175,9±3,1
Mean mass of tramadol 120mg						
MM (mg)	155,8±5,67	154,4±11,5	153,3±7,5	ND	ND	ND

For the mass uniformity test (Table IV), interpretation was based on the determination of two conformity intervals in relation to the average weight.
For all five products analyzed, no individual weight fell outside the corresponding range. We can therefore say that for all five products studied, tablet and capsule weights were consistent within the respective batches analyzed.
This result was comparable to that reported by Papa N'diack in his 1999 study on the Contribution au contrôle de qualité de médicament générique (Contribution to generic drug quality control), where of all five products

analyzed, only one - sulfamethoxypytidazine - had an individual weight outside the ± 5% margin. The weight of 470.0 mg was below the average (502 mg), with a difference of 6.37%. Nevertheless, the result for this product was still within the standard range [10].
Of the 27 samples identified by TLC, none was devoid of active ingredient, and almost all these samples of the same product migrated at the same frontal ratio as the reference products.
In view of these findings and the risks associated with the various types of non-compliance, we make the following recommendations:
To the Ministry of Public Health:
- Strictly and rigorously apply the legal texts governing the practice of pharmacy;
-Revise the pricing structure and taxes on medicines to make them much more accessible to the population;
Pharmacists: buy only from wholesalers and respect the rules of professional ethics and deontology in their daily practice.
Pharmacists must not allow themselves to be corrupted by traders who are greedy and careless of people's health. They must respect the Galen oath they took, especially the paragraph that states “in no case will I agree to use my knowledge and my state to corrupt morals and promote criminal acts”;
To wholesalers: Respect the conditions of conservation and storage of medicines;
To the general public: obtain supplies from approved dispensaries (pharmacies, etc.)

IV. CONCLUSION

Increasingly, drugs from the illicit market are being consumed in the policies of developing countries. Indeed, these inexpensive products are much more suited to the needs of the population. However, the significant differences in price compared to pharmacy prices mean that their good qualities are often suspected by observers. Thus, at the end of our study, out of 27 samples analyzed, the following results emerged:

- from an identification point of view, all the products analyzed had given a positive result by thin-layer chromatography;
- in terms of galenic testing, tablet weights and capsule contents were consistent for all samples. And in terms of labelling, 17 samples showed non-compliant labels.

In view of the results of our study, political decision-makers must become more involved in the fight against the illicit sale of medicines, and ensure that only medicines of good quality are dispensed in approved pharmaceutical structures.

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