BOARD NOTICE

NOTICE 132 OF 2005

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council intends to publish additional minimum standards to be added to Annexure A of *Rules relating to good pharmacy practice* published on the 17 December 2004 Government Gazette No: 27112 of Board Notice 129 of 2004 in terms of section 35A(b)(ii) of the Pharmacy Act 53 of 1974, as amended.

SCHEDULE

Rules relating to what constitutes good pharmacy practice

1. In these rules "the Act" shall mean the Pharmacy Act 53 of 1974, as amended, and any expression to which a meaning has been assigned in the Act shall bear such meaning.

2. The following minimum standard as published herewith shall constitute an additional standard to be added to Annexure A of the *Rules relating to good pharmacy practice* in accordance with section 35A(b)(ii) of the Act -

- Minimum standards for cholesterol monitoring service
- Minimum standards for control of schedule 6 substances
- Minimum standards for emergency postcoital contraception (EPC)
- Minimum standards for glucose monitoring
- Minimum standards for pregnancy testing service
- Products which may not be sold in a pharmacies
- Minimum standards relating to the approval of tutors and premises for training of pharmacist interns and pharmacist's assistants
- Minimum standard for urine analysis

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Minimum Standards for Cholesterol Monitoring **Service**

ADDITIONAL STANDARDS TO ANNEXURE A OF THE RULES RELATING TO GOOD PHARMACY PRACTICE PUBLISHED ON 17 DECEMBER 2004, BOARD NOTICE 129 OF 2004, GOVERNMENT GAZETTE NUMBER 27112

MINIMUM STANDARDS FOR CHOLESTEROL MONITORING SERVICE

Accuracy and precision of blood cholesterol measurement, which are critical for the classification and referral of screening participants, depend on appropriate quality control and staff training. As these services are professional services, any publicity should comply with the Code of Conduct and Minimum Standards for screening and monitoring services. Before undertaking testing, pharmacists should ensure they are adequately covered by insurance in respect of themselves, their staff and the patients who are being tested.

The following standards must be applied when a cholesterol monitoring service is established in a community pharmacy.

Physical facilities

(a) When taking samples, the performance of screening tests must be done in a private consultation area in the pharmacy.

(b) The consultation area must comply-with the requirements as described in 1.2.13 of the GPP manual.

Equipment

(a) Equipment must be accurate, reliable, simple to use, easily cleaned and easily maintained.

(b) To ensure ongoing accuracy and precision of determinations, a suitable quality control system is used, must be implemented and applied on a regular basis.

(c) A reliable method of testing should be used.

(d) Equipment must be maintained in good order to ensure that performance is not impaired.

Procedure for carrying out the test

(a) The service should be fully explained to the patient before any readings are taken.

(b) Written consent must be sought and obtained before any test is carried out.

(c) All procedures and arrangements should be in accordance with the requirements of the National Health Laboratory for clinical laboratories.

(d) The pharmacist should wash his/her hands and then put on new, clean non-sterile examination gloves.

(e) The site of puncture for sample extraction from the patient's finger should be wiped clean using a sterile alcohol swab,

(f) Allow time for the alcohol to evaporate, otherwise this might interfere with the sample.

(g) Care should be exercised when taking the sample.

(h) Set finger-pricking device at a suitable depth for thickness of skin to puncture.

Minimum Standards for Cholesterol Monitoring Service

ADDITIONAL STANDARDS TO ANNEXURE A OF THE RULES RELATING TO GOOD PHARMACY PRACTICE PUBLISHED ON 17 DECEMBER 2004, BOARD NOTICE 129 OF 2004, GOVERNMENT GAZETTE NUMBER 27112

(i) Place the finger-pricking device on the cleaned puncture site and press activating button.

(j) Time should be allowed for a large enough droplet of blood to develop. The pharmacist must inform the patient that care must be taken to ensure that the blood does not spill or drop.

(k) The patient's droplet sample should be guided to the sample plate and the droplet placed on the blood stick.

(l) The sample area should be saturated with the blood to ensure an accurate reading.

(m) Record the Total Cholesterol and where possible the HDL reading immediately.

(n) Where results are not within the desirable range, in addition to providing counselling and advising medical consultation where appropriate, pharmacists should provide suitable printed information leaflets where these are available.

(o) Wipe and clean equipment with alcohol swabs. Dispose of waste from the procedures in front of patient – they can therefore be assured that the cleaning happens after each patient and can witness the procedure in order to achieve confidence in the service.

Interpretation of results

(a) The result of the test should be provided in writing on a standard form. Where the results are not within a desired range, the patient's consent must be sought for this information to be sent to his/her GP. If a patient does not give permission for the pharmacist to contact his/her GP, he/she must be advised to seek medical advice, and must be supplied with the results in writing.

(b) The form should be dated and signed by the pharmacist, with the name and address of the client provided.

(c) At all stages, before and during and after the test, the patient should be kept fully informed about the process and implications of the test and be given opportunities to ask questions.

(d) A single elevated cholesterol measurement does not establish the diagnosis of high blood cholesterol; two or more cholesterol measurements are needed before the diagnosis of high blood cholesterol.

(e) Pharmacists are advised to be careful not to make any diagnostic decisions when undertaking cholesterol testing.

(f) The patient's medical practitioner has the clinical responsibility for the diagnosis and subsequent clinical responsibility for the treatment of the patient.

Documentation and record keeping

(a) The pharmacist must retain a written record of the result of the test, together with the following information –

* the type of test
* batch number of the test material,
* advice or referral given to the patient

for at least three years.

(b) Such records must be stored safely to preserve confidentiality.

Confidentiality

The pharmacist must keep all information provided by the patient and the result of the test, confidential and only disclose information with the consent of the patient.

Waste Disposal

(a) Dressings, swabs and other contaminated wastes from treatment areas should be placed in a suitable clinical waste storage bag or bin with a suitable plastic liner at the point of generation.

(b) Liner bags should be removed at least daily or when three-quarters full. They should be securely fastened with adhesive plastic tape before removal and deposited in a clinical waste storage bag – which should also be securely fastened. The waste should then be sent for incineration.

(c) Syringes, needles and cartridges should be discarded intact and placed in a suitable 'sharps container', which when full should be sealed and placed into a chemical waste bag for storage prior to removal and disposal by incineration,

Counter infection measures

All procedures and arrangements should be in accordance with the requirements of the National Health Laboratories for clinical laboratories. The main counter-infection measures, where applicable, should include:

(a) Preventing puncture wounds, cuts and abrasions in the presence of blood and body fluids, and protecting existing wounds, skin lesions, conjunctivae and mucosal surfaces (aseptic hand washing techniques, use of an appropriate antiseptic etc, gloves, spillage procedures and cleaning procedures).

(b) Applying simple protective measures designed to avoid contamination of the person or clothing and using good basic hygienic practices, including regular hand washing.

(c) Controlling surface contamination by blood by ensuring containment and disinfection.

(d) Avoiding the use of sharps where possible but where their use is essential, exercising particular care in handling and disposal.

(e) Disposing of clinical waste in accordance with Standard Operating Procedures.

Minimum standards for control of specified schedule 5 and schedule 6 substances

ADDITIONAL STANDARDS TO ANNEXURE A OF THE RULES RELATING TO GOOD PHARMACY PRACTICE PUBLISHED ON 17 DECEMBER 2004, BOARD NOTICE 129 OF 2004, GOVERNMENT GAZETTE NUMBER 27112

MINIMUM STANDARDS FOR CONTROL OF SCHEDULE 6 SUBSTANCES

Control of specified Schedule 5 and Schedule 6 substances are of such nature that only persons authorised in terms of the Medicine Act have access to these substances.

(a) Schedule 6 substances must be stored in designated places under lock and key at all times.

(b) The key must be in personal possession of an authorised person responsible for the control of Schedule 6 substances.

(c) A register of 6 must be kept and shall be balanced so as to show clearly the quantity of every specified Schedule 5 or schedule 6 substances remaining in stock as on the last day of March, June, September and December of each year and such balancing shall be completed within 14 days following each said dates.

(d) A pharmacist's assistant shall not handle any Schedule 6 substances except for the purpose of dispensing under the direct personal supervision of pharmacist,

ADDITIONAL STANDARDS TO ANNEXURE A OF THE RULES RELATING TO GOOD PHARMACY PRACTICE PUBLISHED ON 17 DECEMBER 2004, BOARD NOTICE 129 OF 2004, GOVERNMENT GAZETTE NUMBER 27112

MINIMUM STANDARDS FOR EMERGENCY POSTCOITAL CONTRACEPTION (EPC)

INTRODUCTION

Emergency post-coital contraception (EPC) is often referred to as the 'morning after pill'. Emergency contraceptive pills are birth control pills used in high doses, taken within 72 hours of unprotected sex. The EPC will not be effective if the woman is pregnant already, although it is not considered to be harmful to the foetus.

EPC can alter the timing and type of bleeding of the next menstrual period. Bleeding may start a little early or a little late, but if it is more than five days late then pregnancy is a possibility and further referral is necessary. EPC is not as effective as conventional methods of contraception and is not recommended for regular use.

Emergency contraception should not be used in patients with a history of blood clots. Women with diabetes, liver disease, heart disease, kidney disease, or high blood pressure require special consideration.

BEFORE TESTING (PHARMACIST MUST CONSIDER THE FOLLOWING BEFORE SUPPLYING EPC)

(a) The following information must be obtained from the patient prior to the supply of EPC to the patient (in addition to that required in the course of dispensing a prescription):

- certainty that the patient does not want to become pregnant;
- date of patient's last menstrual period to rule out established pregnancy;
- the time that has elapsed since unprotected intercourse occurred (less than 72 hours is more likely to prevent pregnancy);
- whether the patient has been a victim of sexual assault.

(b) To assess how likely it is that the woman might be pregnant, the following questions could be asked:

- Is your period late? How late?
- Was your last period lighter or shorter than normal?
- Was your last period unusual in any other way?
- At any time before this occasion and since your last period, have you had unprotected sexual intercourse?

If the woman answers 'yes' to any of these questions, then a referral, or a pregnancy test, should be recommended.

Supply of EPC could, however, be considered for a woman who, in addition to this current incident of unprotected sexual intercourse, has had within her current cycle previous incidents of unprotected intercourse since pregnancy may not have resulted from these, but could now.

Emergency Contraception Regimens

(a) Emergency contraception regimens consist of two doses of oral contraceptive tablets.

Minimum Standards for Emergency Postcoital Contraception (EPC)

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(b) The first dose is administered within 72 hours of unprotected intercourse., The second dose is taken 12 hours later. Studies support the administration of the first dose within 72 hours after unprotected intercourse.

(c) Dose: The number of tablets taken depends on the product used.

(d) The timing of the first dose of medication is critical. The regimen becomes completely ineffective by day 6 or 7 when implantation usually occurs.

(e) The sooner after unprotected intercourse the tablets are taken, the more effective they will be.

(f) Generally a total of 0.10 or 0.12mg ethinylestradiol and 0.5 or 0.6mg levonorgestrel are taken with each dose. Examples of regimens include:

- 2 tablets of Ovral®: each tablet contains 250ug d-norgestrel/500 ug ethinylestradiol
- 2 tablets E-gen-c® each tablet contains levonorgestrel 0.25mg ethinylestradiol 0.05mg
- Norlevo® which contains 2 X levonorgestrel 0,75mg per tablet

Use of EPC when breastfeeding

Small amounts of levonorgestrel may appear in breast milk. While not considered harmful, to reduce the amount that the baby might ingest, the woman can be advised either to express milk immediately before taking the EPC or to delay taking the medicine until immediately after feeding the baby. This approach must be weighed against the need to minimise delays in treatment.

Professional and ethical responsibility of pharmacists in the provision of EPC

Pharmacists must ensure that the following standards are observed in the supply of EPC as an over-counter-medicine in a pharmacy.

(a) As with all medicines, the pharmacist who supplies EPC must have sufficient knowledge of the product to enable him/her to make an informed decision when requests for EPC are made.

(b) A pharmacist must deal with the request personally and decide whether to supply the product or refer the patient to another appropriate healthcare professional.

(c) Pharmacists must ensure that all necessary advice and information is provided to enable the patient to assess whether to use the product suggested/supplied.

(d) Requests for EPC should be handled sensitively with due regard being given to the customer's right to privacy.

(e) Only in exceptional circumstances should pharmacists supply the product to a person other than the patient.

(f) Pharmacists should, whenever possible, take reasonable measures to inform patients of regular methods of contraception, disease prevention and sources of help.

(g) To help reduce patient stress and anxiety, it is crucial that pharmacists remain supportive and refrain from making judgemental comments or indicating disapproval by means of body language or facial expressions while discussing EPC.

Minimum Standards for Emergency Postcoital Contraception (EPC)

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(h) Supportive pharmacist attitudes, including respect for population diversity and patient beliefs, will also improve compliance and promote effective patient-pharmacist communication if follow-up is needed.

(i) Pharmacists must bear in mind that patients seeking EPC may be under stress after unprotected intercourse for many reasons which may include:

- fear of becoming pregnant;
- embarrassment at failing to use contraceptives effectively;
- general embarrassment about sexual issues;
- lack of knowledge about EPC;
- rape and/or sexual abuse trauma;
- concern about auto-immune deficiency syndrome (AIDS) and sexually transmitted infections (STIs);
- worry about missing the narrow window of opportunity for EPC; or
- a combination of these factors.

(j) Pharmacists who do not wish to provide EPC treatment for personal reasons should maintain objectivity and remain professional when dealing with patients. In this case. patients must be referred to an alternate source of EPC.

(k) If the patient questions the pharmacist as to why he or she will not be providing the product or service personally, the pharmacist should answer in a manner that does not make the patient feel uncomfortable.

(l) Alternate sources for EPC might include referral to one or more prearranged options such as:

- another pharmacist in the same pharmacy;
- another pharmacy in the vidnity;
- a medical practitioner:
- a nearby hospital, community health centre, primary health care clinic or reproductive health clinic.

Confidentiality

It is important *that* all pharmacy staff, including pharmacists, pharmacist interns, pharmacist's assistants and any staff who may be the first contact for the patient be informed of the EPC service available at the pharmacy. Adequate training of personnel in the pharmacy is advocated in the handling of patients seeking these services

(a) All staff must show sensitivity and ensure confidentiality.

(b) The test should be conducted in a private counselling area,

(C) In the testing and counselling: -

- use non-specific language to refer to sensitive terms (e.g. use "the incident" or the "situation" rather than saying 'unprotected intercourse' or "sex")
- use a written form to collect key information about the patient's situation

PATIENT COUNSELLING

General principles

(a) Through the course of counselling, it may become evident that a referral is needed to a medical practitioner, reproductive health clinic etc.

(b) If the EPC product comes with a pregnancy test, it is meant to be used to rule out a pregnancy that may have occurred since her last menstrual period.

(c) The pharmacist should refer to the patient information leaflet and ensure that she understands how to use the pregnancy test correctly.

(d) Women must be counselled to take the first dose of EPC as soon as it is convenient, keeping in mind the timing of the second dose. For example, rather than encouraging the patient to take the first dose at 16h00 (with the second dose at 04h00), it might be better to suggest that she takes the first dose at 19h00.

(e) The pharmacist must explain that emergency contraception does not protect against or treat sexually transmitted infections (STIs). If the patient thinks she may have contracted a STI, she will need to see a medical practitioner immediately.

(f) The pharmacist must remind the patient that EPC is not 100% effective and will not terminate an established pregnancy. If her period does not commence within three weeks, she should consider having a pregnancy test.

(g) The patient should be advised that her period will probably come on time but may be a few days earlier or later than normal.

(h) The pharmacist must emphasise that emergency contraception is for emergency use only and that it is less effective than other means of birth control if used repeatedly.

(i) The patient must be reminded to begin using ongoing contraception as soon as she resumes intercourse. She may be at high risk of pregnancy following EPC use if ovulation is delayed. If her regular method of contraception failed, the patient must be counselled on an effective method to use if necessary.

(j) The patient must be supplied with a patient information leaflet containing instructions, as well as the pharmacy phone number. She must be encouraged to call if she has any further questions.

Continued contraception

(a) Emergency contraceptives are meant solely for emergency use and are not as effective as other birth control methods for ongoing contraception. Pharmacists should encourage patients to talk to a medical practitioner or nurse about using an ongoing contraceptive method to prevent pregnancy in the future.

(b) If the patient does not have a regular health care provider, the pharmacist can offer referrals to local providers.

(c) Women should be told that EPC will not provide continued protection against pregnancy for the remainder of the menstrual cycle, and be advised about other contraceptive measures – including recommending referral where appropriate.

(d) A woman seeking EPC because she has missed one or more oral contraceptive pills should be advised to continue taking her Dills as normal. In addition she should be advised to use a barrier method of contraception for the next seven days.

Referral

The woman should be advised to see her doctor or reproductive health clinic for a pregnancy test if her next period is more than five days late or is unusual in any way or, for those taking an oral contraceptive, if there is no bleed in the pill-free interval.

Minimum standards for Emergency Postcoital Contraception (EPC)

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Repeated use of emergency contraception

(a) Although experience has shown that very few women request emergency contraception repeatedly, mainly because of the unpleasant side effects some women experience while using them, patients should be asked if they have used emergency contraception before, and should be counselled accordingly.

(b) Because EPC is less effective at preventing pregnancy than typical use of regular contraceptive methods, a patient presenting repeatedly for emergency contraception should be provided with treatment but informed of the high cumulative failure rate with repeated use, and provided with referrals for ongoing care.

HIV and Sexually Transmitted infections (STIs)

(a) Patients must understand that EPC does not protect against STIs, including HIV/AIDS and that use of a condom is necessary to protect against these infections.

(b) Patients may be very concerned about possible infection, especially in *cases* of rape. Counselling on this topic is essential, with referral for diagnosis and treatment provided when needed.

(c) Medical referral may be necessary to screen for infections. For this purpose, patients should be advised to schedule a follow-up appointment with a medical practitioner or reproductive health or sexual health clinic after taking the EPC.

(d) If appropriate, the pharmacist should provide information (e.g. leaflets) on sexual health and STIs.

Alcohol/drugs

In some cases the patient may not remember whether penetrative sex took place or not. In such cases, it is best to assume that intercourse occurred and provide emergency contraceptives.

Dealing with children and parents

Parents often have inaccurate information about their child's contraceptive use. Parents may react with anger if they find oral contraceptives, condoms, or a product for emergency contraception in the child's personal belongings because these indicate a level of sexual activity of which they were not aware.

They may also feel displaced because the child did not first discuss the matter with them. Sometimes the provider (e.g. pharmacist, nurse) becomes the primary target of the parent's feelings.

(a) In such cases pharmacists must first be able to address the parent's immediate concerns and provide accurate information about contraceptives, and then address their questions. In talking with parents, pharmacists should keep the following objectives in mind:

- Be direct, honest and professional;
- Tell parents that you understand their concern;
- Inform parents that minors can consent to contraceptive and reproductive health services and it is the pharmacist's obligation to provide them.

(b) If the pharmacist becomes aware that a child (any one under the age of 16) has been physically harmed, sexually abused or sexually exploited by a parent or other person, the pharmacist must report these circumstances to the appropriate local/provincial authority.

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MINIMUM STANDARDS FOR GLUCOSE MONITORING

Definition

Blood glucose monitoring is the measurement of glucose in the blood that can be done at any time on a portable machine. It can be used as a self-test for the diabetic.

Alternative names

Glucose monitoring;
Random glucose;
Glucose - random;
Serum glucose - random

Why the test is performed

(a) This test is used as a screening test for blood glucose levels.

(b) It may be used screen for diabetes

(c) The test allows the diabetic to carefully monitor blood glucose levels to assure that they are within the normal range.

(d) It may be used to monitor control in patients who have diabetes and to detect uncontrolled diabetic patients

(e) The individual can then respond quickly to high or low blood sugar levels with appropriate intervention.

The following standards must be considered when a glucose monitoring service is established in a community pharmacy:

Physical facilities

(a) The taking of samples for the performance of screening tests must be done in a private consultation area in the pharmacy

(b) The consultation area must comply with the requirements described in 1.2.13 of the GPP manual.

Equip*ment*

The following aspects must be considered in glucose monitoring tests:

(a) Equipment must be accurate, reliable, simple to use, easily cleaned and easily maintained.

(b) Accuracy and precision of blood glucose measurements, which are critical for the classification and referral of screening participants, depends on appropriate quality control and staff training.

To ensure ongoing accuracy and precision of determinations, a suitable quality control system is used, must be implemented and applied on a regular basis

Minimum standards for Glucose Monitoring

ADDITIONAL STANDARDS TO ANNEXURE A OF THE RULES RELATING TO GOOD PHARMACY PRACTICE PUBLISHED ON 17 DECEMBER 2004, BOARD NOTICE 129 OF 2004, GOVERNMENT GAZETTE NUMBER 27112

(c) The use of calibration and control solutions by the pharmacist shall assure accuracy of results.

(d) The user should know whether the instrument is calibrated to whole blood or plasma glucose.

(e) Equipment must be maintained in good order to ensure that performance is not impaired.

Performance *of* the test

(a) The service should be fully explained to the patient before any readings are taken.

(b) Written consent from the patient must be sought and obtained before any test is carried out.

(c) It is important to have all test items within reach before starting the test

(d) All procedures and arrangements should be in accordance with the requirements of the National Health Laboratory for clinical laboratories.

(e) The pharmacist should wash his/her hands and then put on non-sterile examination gloves

(f) The site of puncture for sample extraction from the patient's finger should be wiped clean using a sterile alcohol swab.

(g) Allow time for the alcohol to evaporate, otherwise this might interfere with the sample.

(h) Care should be exercised when taking the sample and correct procedure must be followed or the results will not be accurate.

(i) Set finger-pricking device at a suitable depth for thickness of skin to puncture.

(j) Place the finger-pricking device on dean sample area and press activating button.

(k) Time shouid be allowed for a large enough droplet of blood to develop. The operator must inform the patient that care must be taken to ensure that the blood does not spill or drop.

(l) The patient's blood droplet shoutd be guided to a reagent strip, which uses a chemical substance to react to the amount of glucose in the blood.

(m) When using enzyme impregnated strips for glucose measurement it is imperative that the strips are properly stored in the screw cap airtight container provided until use, to ensure for maximum shelf life.

(n) The reagent strip should be saturated with the blood to ensure an accurate reading.

(o) The meter then reads the strip and displays the results as a number on a digital display

(p) Newer monitors can use blood from other areas of the body besides the fingers, reducing discomfort.

(q) Record the glucose reading immediately.

Minimum standards for Glucose Monitoring

ADDITIONAL STANDARDS TO ANNEXURE A OF THE RULES RELATING TO GOOD PHARMACY PRACTICE PUBLISHED ON 17 DECEMBER 2004, BOARD NOTICE 129 OF 2004, GOVERNMENT GAZETTE NUMBER 27112

(r) Patients must be provided with the results in a written form. Where the results are not within a desired range, the patient's consent must be sought for this information to be sent to his/her. If a patient does not give permission for the pharmacist to contact his/her GP, he/she must be advised to seek medical advice, and must be supplied with the results in writing

(s) Where results are not within the desirable range, in addition to providing counselling and advising medical consultation where appropriate, pharmacist should provide suitable printed information leaflets where these are available.

(t) Before undertaking testing, pharmacists should ensure they are adequately covered by insurance in respect of themselves, their staff and the patients who are being tested.

(u) Dispose of waste from the procedures in front of patient who can therefore be assured that the cleaning happens after each patient and can witness the procedure in order to achieve confidence in the service.

Interpretation of results

(a) The result of the test should be provided in writing on a standard form.

(b) The form should be dated and indicate the name and address of the client.

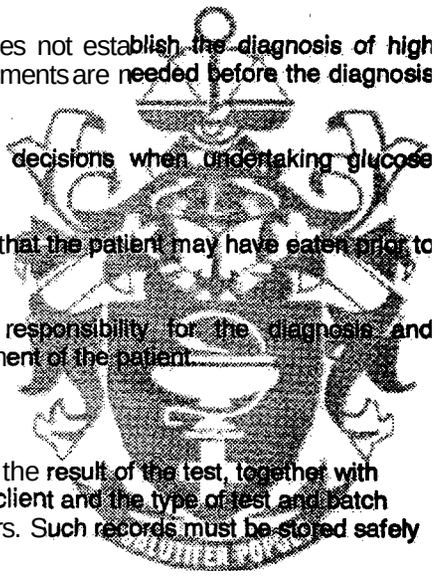
(c) At all stages, before and during and after the test, the patient should be kept fully informed about the process and implications of the test and be provided with the opportunity to ask questions.

(d) A single elevated glucose measurement, does not establish the diagnosis of high blood glucose, two or more glucose measurements are needed before the diagnosis of high blood glucose.

(e) Pharmacists may not make any diagnostic decisions when undertaking glucose testing

(f) Pharmacists must take into account any food that the patient may have eaten prior to the test, when interpreting the results.

(g) The medical practitioner has the clinical responsibility for the diagnosis and subsequent clinical responsibility for the treatment of the patient.



Documentation and record keeping

(a) The pharmacist must retain a written record of the result of the test, together with information and consent form provided by the client and the type of test and batch number of the test materials, for at least 3 years. Such records must be stored safely to preserve confidentiality.

Confidentiality

(a) The pharmacist must keep all information provided by the patient and the result of the test confidential and only disclose information with the consent of the patient.

Minimum Standards for Pregnancy Testing Service

ADDITIONAL STANDARDS TO ANNEXURE A OF THE RULES RELATING TO GOOD PHARMACY PRACTICE PUBLISHED ON 17 DECEMBER 2004, BOARD NOTICE 129 OF 2004, GOVERNMENT GAZETTE NUMBER 27112

MINIMUM STANDARD FOR PREGNANCY TESTING SERVICE

The following standards must be considered when a service offering performance of pregnancy tests is established in a community pharmacy

Physical facilities

(a) The performance of pregnancy tests must take place in a private consultation area in the pharmacy.

(b) A clean toilet facility attached to the pharmacy is a necessity for the production of a urine sample

(c) The consultation area must comply with the requirements described in section 1.2.13 of the GPP manual.

(d) A reliable method of testing must be used.

Procedure, interpretation and provision of results

The following aspects must be considered in pregnancy testing:

(a) The procedure must be explained to the patient, her permission obtained and the patient made to feel at ease.

(b) A signed and dated confirmation of the request for the test should be obtained.

(c) The form on which confirmation is obtained should state the limits of accuracy of the test.

(d) All questions, relating to the test, must be asked by the pharmacist and the answers recorded in writing.

(e) A Standard Operating Procedure, to be available in the pharmacy for inspection, must be devised and followed to ensure that no confusion occurs between samples.

(f) Care must be taken to prevent contamination, which can result from the handling of samples of urine.

(g) Persons carrying out tests should wash their hands before leaving the consultation area.

(h) Any cuts and grazes on hands or on exposed parts of the body must be covered with waterproof dressings.

(i) The result of the test must be provided in writing on a standard form.

(j) The form must be dated, signed by the pharmacist, and bear the name and address of the dient.

(k) The result should be given as positive or negative with an explanation of such terms and the limits of accuracy of the test, (refer earlier comment) e.g: "The specimen provided has been tested for urinary gonadotrophin and has been found to be: Positive / Negative. A positive result indicates a probable pregnancy".

(l) At the request of the client, a copy of the form should be sent to her medical practitioner.

Minimum Standards for Pregnancy Testing Service

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(m) Not withstanding the result of the test, the client should be strongly advised to consult her medical practitioner or reproductive health service.

Documentation and record keeping

The pharmacist must retain a written record of the result of the test, together with information and consent form provided by the client and the type of test and batch number of the test materials, for at least 3 years. Such records must be stored safely to preserve confidentiality.

Confidentiality

The pharmacist must keep all information provided by the patient and the result of the test confidential and only disclose information with the *consent* of the patient.

Minimum Standards for Products not in a Pharmacy

ADDITIONAL STANDARDS TO ANNEXURE A OF THE RULES RELATING TO GOOD PHARMACY PRACTICE PUBLISHED ON 17 DECEMBER 2004, BOARD NOTICE 129 OF 2004, GOVERNMENT GAZETTE NUMBER 27112

PRODUCTS WHICH MAY NOT BE SOLD IN A PHARMACY

The following **may not be sold** in the pharmacy:

(a) Arms and ammunition;

(b) Fireworks;

(c) Tobacco, snuff, cigarettes and tabacco related products;

(d) Liquor, except when meant for medicinal purposes and

(e) Lotto tickets

Minimum Standards for Urine Analysis

ADDITIONAL STANDARDS TO ANNEXURE A OF THE RULES RELATING TO GOOD PHARMACY PRACTICE PUBLISHED ON 17 DECEMBER 2004, BOARD NOTICE 129 OF 2004, GOVERNMENT GAZETTE NUMBER 27112

MINIMUM STANDARD FOR URINE ANALYSIS

Urine analysis can be used to detect and measure the level of a variety of substances in the urine, including leucocytes, nitrite, urobilinogen, protein, pH, blood, specific gravity, ketones, bilirubin and glucose. These tests use a thin strip of plastic (dipstick) impregnated with chemicals that react with substances in the urine and change colour. For confirmation, the test may need to be repeated with more sophisticated and accurate laboratory analysis of the urine, in which case the patient should be referred to a medical practitioner

Physical facilities

(a) A clean toilet facility attached to the pharmacy is essential.
(b) Screening tests must be performed in a private consultation area in the pharmacy.
(c) The consultation area must comply with the requirements as described In 1.2.13 of the **GPP** manual.

Equipment

Urine sample must be collected in a suitable dean container, which should be supplied, to the patient.

Procedure for carrying *out* the test

The following aspects must be considered in urine testing:

(a) The procedure must be explained to the patient, her/his permission obtained and the patient made to feel at ease.

(b) A signed and dated confirmation of the request for the test must be obtained.

(c) The form on which confirmation is obtained should state the limits of accuracy of the test.

(d) All questions that the patient or the patient's caregiver may have, relating to the test, must be answered by the pharmacist and the answers recorded in writing.

(e) A Standard Operating Procedure, to be available in the pharmacy for inspection, must be devised and followed to ensure that no confusion occurs between samples.

Obtaining a Clean-Catch Urlne Sample

The following information and procedure for obtaining a clean-catch urine sample must be explained to the patient or the patient's caregiver:

(a) The procedure is quite simple; there is usually no fluid or food restriction before the test.

(b) The head of a man's penis or the opening of a woman's urethra is cleansed, usually with a small pad that contains an antiseptic substance.

(c) The first few drops of urine are allowed to flow into the toilet, washing out the urethra.

(d) Patient must collect the mid-stream urine in a sterile container.

(e) The last few drops of urine are allowed to flow into the toilet.

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Storage and testing of samples

(a) Contamination of testing material and samples must be prevented.

(b) Urine samples must be stored at room temperature and tested in less than 4 hours after collection.

(c) Urine must not be exposed to direct sunlight as this may result in the oxidation of bilirubin and urobilinogen.

(d) The testing areas of reagent strips must not be touched by hand or come into contact with the working surfaces or other materials.

(d) Expiry dates of material must be checked before use.

(e) Remove one strip at a time and replace the lid immediately.

(f) **Strips must be checked for any discolouration or darkening of material which could be an indication of deterioration of the reagent strips.**

(f) Dip the test strip into fresh urine for approximately 2 seconds.

(g) Drain excess urine on the rim of the container in which the urine was coltected. Remove excess urine by briefly blotting the side of the strip on absorbent tissue.

(h) After 30-60 seconds (60-120 seconds in the case of the leucocytes test patch), compare the test strip with the colour scale or the colour grades on the label.

(i) NB: Colourations which appear only along the edges of the test patches, or develop after more that two minutes, do not have any diagnostic significance.

(j) Persons carrying out tests should wash their hands before leaving the consultatior area.

(k) Any cuts and grazes on hands or on exposed parts of the body must be covered with waterproof dressings.

Interpretation of results

(a) The result of the test should be provided to the patient or his/her caregiver in writing on a standard form, which includes the date and the name and address of the patient, and which is signed by the pharmacist.

(b) Where the results are not within the desired range, the patient's consent must be sought for this information to be sent to his/her medical practitioner. "If a patient does not give permission for the pharmacist to contact his/her GP, he/she must be advised to seek medical advice, and must be supplied with the results in writing.

(c) Abnormal findings indicate certain problems e.g.

Protein: Protein in the urine (proteinuria) can usually be detected quickly by using a dipstick. Protein may appear constantly or only intermittently in the urine, depending on the cause. Proteinuria is usually a sign of kidney disorders. Proteinuria may be benign or pathological.

Abnormal protein values may be Indicative of

Benign proteinuria

- postural
- excessive exercise
- high or low temperature
- during pregnancy

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Pathological proteinuria
External
- colic
- liver cirrhosis
- plasmacytoma
- cardiac insufficiency

Renal
- pyelonephritis
- glomerulonephritis

Glucose: Glucose in the urine (glucosuria) can be detected accurately by dipstick. The most common cause of glucose in the urine is diabetes mellitus.

Abnormal glucose values may be indicative of
- Renal Glycosuria
- Diabetes Mellitus
- Renal glycosuria during pregnancy
- Excessive consumption of carbohydrates

Ketones: Ketones in the urine (ketonuria) can be detected by dipstick. Ketones are formed when the body breaks down fats, rather than glucose are used to produce energy. Ketones are harmful to the body if allowed to accumulate.

Abnormal ketones values may be Indicative of
- Diabetic ketoacidosis
- Insulin overdose
- Insufficient food intake
- Nausea and vomiting
- Starvation
- Strict dieting
- Severe stress
- Severe fever due to infection

Blood: Blood in the urine (haematuria) is detectable by dipstick and confirmed by microscopic examination of the urine, and other laboratory tests. Sometimes there is enough blood in the urine to be visible, making the urine appear red or brown. The patient must be referred to a medical practitioner when blood cells or haemoglobin are detected in urine, as it is of pathological significance.

Abnormal blood / haemoglobin values may be indicative of:
Haematuria (blood in urine)
- kidney and bladder calculi
- damage to kidney or urinary tract

Haemaglobinuria(haemoglobin in urine)
- breakdown of red blood cells
- poisoning

Myoglobinuria
- myocardial infarct
- muscledamage

Nitrites: Nitrites in the urine (nitrituria) are also detectable by dipstick. High nitrite levels indicate urinary tract infection.

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Abnormal nitrite values may be indicative of

Bacterial infection
- E Coli
- Salmonella
- Citrobacter
- Proteus
- klebsiella

Leukocyte Esterase: Leukocyte esterase (an enzyme found in certain white blood cells) in the urine can be detected by dipstick. Leukocyte esterase is a sign of inflammation, which is most commonly caused by a urinary tract infection.

Abnormal leukocytes values may be indicative of

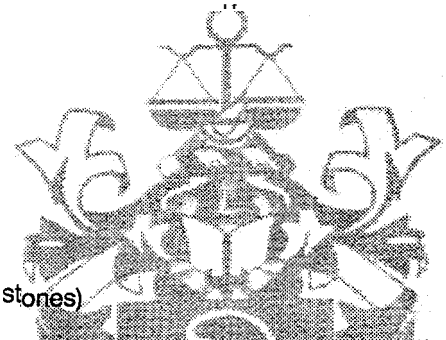
- kidney infection
- cystitis
- urethritis
- contamination
- vaginal secretion

pH levels in urine: The acidity or alkalinity of urine is measured by dipstick. Certain foods and metabolic disorders may change the acidity of urine.

Abnormal pH values may be indicative of

Persistent alkaline urine (pH 7 - 8)
- suggests urinary tract infection
- vegetarian diet
- alkalosis
- pyloric stenosis/ obstruction
- vomiting
- alkalizing drugs

Persistent acid urine (pH 5 - 7)
- gout
- fever
- phenacetin intake
- predisposition to uric acid calculi (kidney stones)



Concentration: The concentration of urine (also called the osmolality or specific gravity) may be important in diagnosing abnormal kidney function. The kidneys lose their capacity to concentrate urine at an early stage of a disorder that leads to kidney failure. In one special test, a person drinks no water or other fluids for 12 to 14 hours; in another, a person receives an injection of antidiuretic hormone. Afterward, urine concentration is measured. Normally, either test should make the urine highly concentrated. However, in certain kidney disorders (such as nephrogenic diabetes insipidus), the urine cannot be concentrated even though other kidney functions are normal.

Abnormal specific gravity values may be indicative of

Reduced specific gravity
- diabetes insipidus
- certain renal diseases
- excess fluid intake
- diabetes mellitus

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Raised specific gravity

- dehydration
- adrenal insufficiency
- nephrosis
- congestive cardiac-failure
- liverdisease
- Constant specific gravity
- chronic renal disorder

UROBILINOGEN: When abnormal values of urobilinogen are found during a urine test, further investigation is required to ascertain patient's health status.
In the intestines bacteria form urobilinogen from bilirubin. This is then absorbed and passes to the liver and urine.

Abnormal urobilinogen values may be indicative of

Increased values

- overburdening of the liver
- excessive RBC breakdown
- increased urobilinogen production
- re-absorption - a large hematoma
- restricted liver function
- hepatic infection
- poisoning
- liver cirrhosis
- Low values
- failure of bile production
- obstruction of bile passage

BILIRUBIN: Bilirubin levels in urine is a result of haemoglobin breakdown. In the live bilirubin is conjugated to an acid to make conjugated bilirubin. Unconjugated bilirub is water soluble and can therefore be excreted in urine.

Abnormal bilirubin values *may* be Indicative of:

Pre-hepatic condition

- anaemias,
- excessive breakdown of RBC,

Hepatic condition

- hepatitis,
- cirrhosis,
- obstruction of biliary duct,
- toxic *liver* damage

Post-hepatic condition

- biliary tree obstruction

Documentation and *record* ***keeping***

(a) The pharmacist must retain a written record of the result of the test, together with information provided by the patient, the type of test used and the batch number of the test material, for at least one year.

(b) Such records must be stored safely to preserve confidentiality.

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Confidentiality

The pharmacist must keep all information provided by the patient and the result of the test, confidential and only disclose information with the consent of the patient.

Minimum standards relating to the approval of tutors
and premises for training of pharmacist Interns and pharmacist

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MINIMUM STANDARDS RELATING TO THE APPROVAL OF TUTORS AND PREMISES FOR TRAINING OF PHARMACIST INTERNS AND PHARMACIST'S ASSISTANTS

Criteria for approval of tutors of pharmacist interns

Council applies the following criteria in the approval of tutors and premises for the training of pharmacist interns:

(a) In terms of the Pharmacy Act, an internship can only be undertaken at a pharmacy or institution approved by Council.

(b) The prospective tutor must have had at least three years' experience as a pharmacist.

(c) This requirement may be relaxed in circumstances where the prospective tutor or organisation submits an acceptable motivation. In such cases the prospective tutor must have at least two years' experience (pharmaceutical community service included).

(d) The prospective tutor must convince the Registrar that he/she is abreast of professional knowledge in order to maintain a high standard of competence relative to his/her activity.

(e) A pharmacist with a suspended sentence may not act as a tutor.

(f) The prospective tutor must demonstrate that sufficient activities relating to the scope of practice of pharmacists are performed in the pharmacy, in order to ensure sufficien exposure of the intern to the practice of the profession.

(g) The approved tutor must practise full-time at the premises where the internship wil take place.

(h) Pharmacists who practise part-time in a pharmacy (e.g. ¾ positions) cannot act as tutors of pharmacist interns.

(i) If the approved tutor is going to be absent from a pharmacy/institution for more than four (4) weeks, the training of the intern must be delegated to another pharmacist for the period of absence of the tutor. The approved tutor remains responsible for the training of the pharmacist intern, even though delegation has taken place.

Criteria for the approval of pharmacies

The following are considered in the evaluation of an application for approval of a pharmacy for purposes of training:

(a) Whether sufficient activities relating to the scope of practice of pharmacists are performed in the pharmacy, in order to ensure sufficient exposure of the intern to the profession;

(b) Comptiance with the requirements of good pharmacy practice:

(i) The presence of a private or semi-private counselling area where one of the key functions of the pharmacist, namely the provision of advice on the safe and correct use of medicines, can be carried out;

Minimum standards relating to the approval of tutors and premises for training of pharmacist interns and pharmacist

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(ii) Evidence of controlled access of the public to scheduled medicines (including Schedule 2 medicines), and compliance with the legal requirements for record-keeping;
(iii) The availability of sufficient literature sources and/or electronic access to such information;
(iv) The availability of appropriate apparatus and equipment;
(v) Sufficient space in the dispensing area for safe dispensing; and
(vi) The general appearance of the pharmacy.

(c) In the event of the pharmacy moving to new premises or changing ownership, the approval of the tutor(s) and pharmacy lapses.

(d) The tutor(s) involved must re-apply for approval as a tutor and for the approval of the pharmacy for training purposes.

Internship programme in hospital complexes (Public sector hospital complexes)

Interns may be allowed to rotate in hospital complexes (i.e. where hospitals have been grouped together in health care complexes and/or provide health care services in collaboration with community health care centres or primary health care clinics) under the following conditions:

(a) There must be at least one approved tutor to be responsible for the effective practical training of the pharmacist intern concerned;

(b) Facilities (hospital pharmacies) where the intern will be rotating must be approved and recorded by Council and each facility must have a pharmacist to supervise the internship;

(c) The facility (hospital pharmacy) where such rotation would take place for purposes of practical training, the period(s) that such services would be provided, as well as the name of the pharmacist under whose supervision the intern would work, must be clearly indicated/described in the contract to be approved by Council before the internship commences;

(d) The rotation must be for purposes of practical training only;

(e) Community Service Pharmacists may be used to supervise training of an intern where rotation takes place;

(f) (refer section on 'Delegation of training by an approved tutor').

An approved tutor may not delegate his supervisory responsibilities to the Community Service Pharmacist.