# AFRICAN JOURNAL OF MEDICINE and medical sciences

VOLUME 30, NUMBERS 1 & 2, MARCH AND JUNE 2001

EDITOR:
B. O. OSOTIMEHIN

ASSISTANT EDITOR:
A. O. UWAIFO

ISSN 1116 — 4077

# Legal and regulatory aspects of prescribing and marketing emergency contraception in Nigeria

**A. O. Adekunle, I.A. Babarinsa, Z. Akinyemi* and A.Y. Okediran†**

*Fertility Research Unit, Department of Obstetrics and Gynaecology, University College Hospital, Ibadan, *The Society for Family Health, Awaiye House, Orile Iganmu, Lagos, †Department of Public and International Law, Faculty of Law, University of Ibadan, Nigeria.*

**Summary**

Emergency contraception remains so little used or understood and the lack of its awareness can be traced to a myriad of factors including legal and regulatory obstacles. The aim of this study was to determine the legal and regulatory aspects of dispensing or marketing a contraceptive method for reasons (especially emergency purposes) other than stated by the manufacturers.

The existing drugs' and devices' regulatory systems in Nigeria, especially those governing family planning methods, were reviewed. A questionnaire was administered to 363 health workers, comprising of physicians, pharmacists, nurses and midwives, to determine the implications of dispensing some currently available oral contraceptives (OCs) for emergency purposes despite the fact that there is no explicit description of emergency use in the labelling of such drugs. In addition, in-depth interviews were conducted with regulatory bodies.

It was observed that, with the exception of Postinor$^R$, the drug manufacturers' leaflets did not indicate that they could be used for emergency contraceptive purposes. Although 64.5% of the healthcare providers were aware that OCs and intrauterine contraceptive devices (IUCDs) can be used for emergency purposes, 42.1% actually prescribed or recommended them. Many health workers (62.3%) were unaware of any legal implication with regards to prescribing unregistered drugs in Nigeria. The existing guidelines stipulate that a manufacturer or marketer should 're-register' a product if a new indication or use not contained in the initial application was found later. To satisfy legal requirements, it does appear that the currently available OCs and IUCDs in Nigeria must be labelled and registered for emergency contraceptive purposes.

**Keywords:** *Practice, legal, regulatory, emergency contraception, health workers, Nigeria.*

**Résumé**

Les methodes contraceptives urgentes restent moins utilisées et comprise et le manqué d'information peut etre due a une myriade de facteurs qui sont legaux a reglementaires. Le but de cette étude etait de determiner les aspects legaux et reglementaires de dispose ou de vendre les contraceptif pour des raisons (particulierement pour des raisons d'urgentes) autre que ceux les fabriquants ont indiques.

Les medicaments et les dispositifs de systeme de regulation au Nigeria, in particulier ceux qui gerent les methods de "planning familial" ont ete revises. Des questionnaires etaient distribuens a 363 travailler de la sante publique a savoir medecins, pharmaciens, infirmiers et sage femmes, pour determiner les implications pour administrer quelques contraceptifs orals courant qui se trouvent en ce moment sur le marche pour des raisons urgentes; malgre le fait qu'il n'ya pas de description explicit concernant l'usage urgente de ses medicaments dans la notice.

Des interviews avaient ete coordonnes en profondeur avec le corps medical reguliers. Il avait ete observe que avec l'exception de postinor$^R$, les notices des medicaments n'indiquaient pas si les contraceptifs pouvant utiliser pour les methode contraceptive urgentes. Neamoins, 64.5% de corps de sante sont au courant du fait que les pillules et les contraceptives intra-uterines peuvent etre utilises pour des raisons urgentes. 42.1% pourcent prescrivent en recommandent ces contraceptifs. Majorite des personnels de la sante (62.3%) ne sont pas informes sur des implications judiciaries qui existent lorsque les medicaments pas recommandes sont peserit au Nigeria. Les textes speculent que un fabricant ou pharmacien doit se faire inserire et enregistrer leur produit, s'il y a de nouvelles indications ou utilisations qui ne figurent pas dans la notice precedante. Pour satisfaire des exigencies legales, il parrait qui les pillules or contraceptives oraux disponible et les contraceptifs intra uterine doivent etre enregistrer et lebeller pour des raisons de contraception urgentes.

Correspondence: Dr. Adeyemi O. Adekunle, Department of Obstetrics and Gynaecology, University College Hospital, Ibadan, Nigeria. Telephone: 234- 2-2413250; 234-2-8102079, 234-2-2410088 ext. 3224, Fax: 234-2-241-3545 or 234-2-241-1768. E-mail: ykadekunle@skannet.com.ng

## Introduction

Emergency contraceptives, also called post-coital contraceptives, are methods that women can use after unplanned and unprotected intercourse to prevent pregnancy [1,2]. Emergency contraception is largely an unknown method: a review of the literature shows a widespread lack of knowledge among both providers and women about emergency contraceptive methods, how to use them, and where to obtain services. The fact that emergency contraception remains so little used or understood can be traced to a myriad of factors such as cultural influences that discourage its provision and use, legal and regulatory obstacles, service delivery obstacles and lack of knowledge [3].

Post-coital contraception has been used for several years in various countries for fertility control [4]. Initially, it consisted of the administration of a single dose of estrogen, such as diethylstilboestrol (DES) within 48 hours of intercourse

until a course-effect relationship between its use early in pregnancy and adenocarcinoma of the vagina and congenital defects of the genital tract in the female offspring of treated women was documented [5]. Thus, other estrogens with comparable efficacy, but without teratogenic effect, such as ethinyl estradiol and conjugated estrogens were utilized [6]. Currently, post-coital methods for emergency use involve either administration of steroid hormones (estrogens or estrogen/progestin combinations), or less commonly, insertion of a copper-releasing IUD. With the Yuzpe regimen, pregnancy can be prevented in up to 99.6% of cases [7,8] and the risk of pregnancy is even lower with post-coital use of an IUD [7]. Luteolytic agents or compounds such as antiprogestins or progestetrone synthesis inhibitors have been attempted, however, their clinical efficacy deserves to be investigated. A new development is the administration of the progestin Danazol as post-coital pill with minimal side effects but failure rates as high as 10% in a limited number of subjects [9]. More promising is the antiprogestin, mifepristone (RU 486) used either as post-coital or on day 27 of the cycle. Side effects with RU 486 are minimal, failure rates ranged from 0 to 1.6% [10,11] and has the convenience of a once-only oral dose.

In Nigeria, oral contraceptive pills are widely available and fairly affordable and in rare instances a physician's prescription may be required. The attention should therefore focus on making oral contraceptive utilisation flexible and purposefully directed at emergency contraception. However, before the use of an existing method of contraception is expanded within a country or community, fundamental issues need to be addressed [12]. Emergency contraceptive pills (ECPs) contain the same hormones that are used in some regular contraceptive pills: an estrogen (ethinyl estradiol) and a progestin (levonorgestrel). However, none of the manufacturers' labels indicates that these regular pills can be used for emergency purposes and although ECPs are being promoted in Nigeria, the drug regulatory authorities are yet to insist on explicit description of emergency use in the labelling of commonly available OCs. The objectives of this study were to determine the implications of dispensing and marketing some currently available OCs as ECPs despite the fact that there is no explicit description of emergency use in the labelling of such drugs, and also to determine the extent to which the information and instructions contained in packages of pharmaceutical products dispensed and marketed as FP methods limit their use as emergency methods.

## Methodology

A provider survey on regulatory and legal aspects of EC was conducted. A semi-structured questionnaire on opinion and prescribing attitudes was administered to healthcare providers who were most likely to prescribe, recommend or dispense OCs as ECPs. The questionnaire was designed to specifically enquire about knowledge, attitude, and practice of contraceptive prescribing, especially for emergency purposes. The first eight questions were to describe selected demographic characteristics of the respondents. Subsequent parts of the questionnaire were to identify the respondents' potential behaviour with regards to prescribing the regular OCs as ECPs, in the absence of specific literature, as to such indication. There were also ten open-ended questions. A pre-testing of the questionnaire was carried out at the University College Hospital, Ibadan among 30 respondents comprising doctors and nurses. Although the questionnaire was not modified after the pre-test, the 30 questionnaires were excluded from the results presented hereafter. The questionnaires were administered by convenience sampling to health workers at hospitals and family planning clinics at Ibadan, Lagos, Jos, and Sagamu. Of the 450 questionnaires sent out, 368 were returned, out of which 363 contained adequate information for computer coding and entry. The data were analysed using the SPSS program.

Secondly, privileged information was sought from officially constituted councils which control pharmaceutical training and practice as well as Federal Government agencies which oversee the safety and acceptability of drugs to which the public is exposed. Although this was intended to be an in-depth interview, it had to be changed into written questionnaires, supplemented by enabling information to the respondents. This was because respondents wanted to cross check documents, and be fairly certain of their pronouncements.

## Findings

*Providers' survey*

Three hundred and sixty-three health workers completed the questionnaire out of 450, thus giving a response rate of 80.7%.

**Table 1:** Characteristics of respondents.

| Characteristic | Number of Respondents Number | Percent |
|---|---|---|
| *Sex of respondents (n = 363)* | | |
| Female | 217 | 59.8 |
| Male | 146 | 40.2 |
| *Profession (n = 363)* | | |
| Physicians | 142 | 39.1 |
| Nurse/Midwife | 176 | 48.5 |
| Pharmacists | 36 | 9.9 |
| Social Worker | 9 | 2.5 |
| *Years of practice in profession (n = 363)* | | |
| < 5 years | 98 | 27.0 |
| 6 - 10 years | 115 | 31.7 |
| > 10 years | 150 | 41.3 |
| *Specialities (n = 363)* | | |
| Obstetrics and Gynaecology | 71 | 19.6 |
| Paediatrics | 11 | 3.0 |
| Surgery | 11 | 3.0 |
| Internal Medicine | 9 | 2.5 |
| General Medical Practice | 48 | 13.2 |
| General Nursing | 73 | 20.1 |
| Midwifery | 46 | 12.6 |
| Pharmacy | 36 | 9.9 |
| Family Planning | 30 | 8.3 |
| Others | 28 | 7.7 |
| *Age of respondents (n = 363)* | | |
| < 30 years | 92 | 25.3 |
| 31 - 40 years | 185 | 51.0 |
| 41 - 50 years | 74 | 20.4 |
| 51 - 60 years | 8 | 2.2 |
| Above 60 years | 4 | 1.1 |
| *Religious affiliation (n = 359)* | | |
| Pentecostal | 183 | 51.0 |
| Protestant | 91 | 25.3 |
| Catholic | 48 | 13.4 |
| Muslim | 26 | 7.2 |
| Traditional | 9 | 2.5 |
| None | 2 | 0.6 |

Table 1 shows the characteristics of the respondents. There were 217 (59.8%) female respondents while the males numbered 146 (40.2%). The majority of the respondents were in the nursing and midwifery profession while 39.1% were physicians. Others were pharmacists (9.9%) and social workers (2.5%). In terms of professional experience, 27.0% had been in practice for five years or less, 31.7% had practiced for six to ten years and 41.3% had been in practice for more than ten years. About half (48.6%) of the respondents were practicing in specialities related to Obstetrics and Gynaecology. The mean age of the respondents was 35.92 years, the female respondents being slightly older than the males. Most of the respondents were Christians (89.7%) with 51.0% of them in the Pentecostal denomination.

**Table 2:** Knowledge and attitudes of respondents towards contraception

| Characteristic | Number of Respondents | |
|---|---|---|
| | Number | Percent |
| *Approval of family planning (n = 363)* | | |
| Yes | 341 | 93.9 |
| No | 10 | 2.8 |
| Indifferent | 9 | 2.5 |
| No response | 3 | 0.8 |
| *Methods of contraception usually* Prescribed or Recommended (n = 350, but *multiple responses accepted)* | | |
| Intra uterine contraceptive device | 89 | 25.4 |
| Natural methods | 45 | 2.9 |
| Condom | 34 | 9.7 |
| Oral contraceptive pill | 15 | 4.3 |
| Vaginal "foaming tablets" | 2 | 0.6 |
| Emergency contraceptive pills | 1 | 0.3 |
| Injectable | 4 | 1.1 |
| Norplant$^{R}$/Uniplant$^{R}$ | 5 | 1.4 |
| Sterilization | 2 | 0.6 |

Table 2 shows that 93.9% of the respondents approved of family planning (FP). Only 2.5% were indifferent. The favourite method of FP usually prescribed or recommended by the respondents was the IUCD (25.4%). Only one respondent indicated that she usually prescribes or recommends ECPs. Respondents who indicated more than one method constituted 43.7% of the sample. Majority of the respondents (63.1%) claimed to be familiar with the guidelines for drug registration in Nigeria (Table 3).

**Table 3:** Awareness of drug registration practices in Nigeria

| Issues | Number of Respondents | |
|---|---|---|
| | Number | Percent |
| *Are you familiar with Guidelines for drug registration in Nigeria? (n = 363)* | | |
| Yes | 229 | 63.1 |
| No | 120 | 33.1 |
| No response | 14 | 3.8 |
| *Knowledge of organisation responsible for drug registration (n = 363)* | | |
| National Agency for Food and Drug Administration & Control (NAFDAC) | 292 | 80.4 |
| Ministry of Health & Social Services | 16 | 4.4 |
| Medical & Dental Council of Nigeria | - | - |
| Pharmaceutical Society of Nigeria | 11 | 3.0 |
| Don't know | 44 | 12.1 |

The National Agency for Food and Drug Administration and Control (NAFDAC) was correctly identified by 80.5% of the respondents as the organisation responsible for drug registration in Nigeria. About 12.1% of the respondents did not know. Related to years of experience, the six-to-ten years category of respondents were slightly more than the two categories, at getting this question right, or not knowing.

**Table 4:** Prescriptive Attitudes of Respondents

| Issues | Number of Respondents Number | Percent |
|---|---|---|
| *Would you study drug information leaflet before prescribing a drug? (n = 363)* | | |
| Always | 181 | 49.9 |
| Sometimes | 174 | 47.9 |
| No response | 8 | 2.2 |
| *Would you prescribe or recommend a drug for conditions other than those indicated in the manufacturer's label? (n = 363)* | | |
| Yes | 109 | 30.0 |
| No | 243 | 66.9 |
| No response | 11 | 3.1 |
| *Reasons for prescribing (n = 105)* | | |
| Manufacturers may not wish to list all indications | 14 | 13.3 |
| Proven clinical efficacy of the drug | 74 | 70.5 |
| Information leaflet may be inadequate | 17 | 16.2 |
| *Reasons for not prescribing (n = 224)* | | |
| Fear of the law | 23 | 10.3 |
| May be risky for the patient/Side effects | 155 | 69.2 |
| Drug may not be effective | 46 | 20.5 |
| *Would you prescribe a drug not registered for use in Nigeria even if aware of its effectiveness? (n = 363)* | | |
| Yes | 114 | 31.4 |
| No | 229 | 63.1 |
| No response | 20 | 5.5 |
| *Reasons for Prescribing Effective but Unregistered Drugs (n =111)* | | |
| May be beneficial to patient | 68 | 61.3 |
| Approval in country of origin | 33 | 29.7 |
| Unaware of prohibitive laws | 10 | 9.0 |
| *Reasons for Not Prescribing Effective but Unregistered Drugs (n = 196)* | | |
| Respect/Fear for the law | 114 | 58.2 |
| May be risky for the patient | 60 | 30.6 |
| May not be available or expensive | 8 | 4.1 |
| May not be properly stored and dispensed | 14 | 7.1 |

Table 4 shows that 49.9% of the respondents would read through the manufacturers' drug information leaflets before prescribing a specific drug while 47.9% claimed to do this from time to time. Majority of the respondents (66.9%) would not prescribe or recommend a drug for conditions other than those listed on the manufacturer's drug information leaflet. Those that would want to do so (30.0%) cited such reasons as awareness of proven clinical efficacy of the drug (70.5%), inability of the manufacturers to list all indications (13.3%) or provide necessary information (16.2%). Those that would refrain from doing so cited such reasons as 'fear of the law' (10.3%), risk of side effects (69.2%) and lack of effectiveness of the drug. It is not without significance to note that 63.1% of the respondents would refrain from prescribing a drug not registered for use in Nigeria even if aware of its effectiveness. Many of the respondents (60.3%) would consider it illegal to prescribe or recommend an unregistered drug even if studies and experience have confirmed its effectiveness (Table 5). Only 34.7% would not consider it illegal. Those who did not consider it illegal cited such reasons as the benefit that may accrue to the patient, inadequate provision of information on the drug leaflet and proven effectiveness, for doing so. However, 6.2% would not consider it illegal do so because they are not aware of any legal limitation.

**Table 5:** Legal implications of prescribing unregistered drugs.

| Issues | Number of Respondents Number | Percent |
|---|---|---|
| *Would you consider it illegal to prescribe or recommend an unregistered drug even if studies and experience have confirmed its effectiveness?* | | |
| Yes | 126 | 34.7 |
| No | 219 | 60.3 |
| No response | 18 | 5.0 |
| *Reasons for considering it illegal (n = 128)* | | |
| Irrational/No legal backing | 56 | 43.7 |
| Would not benefit the patient | 21 | 16.4 |
| May not be safe for the patient | 45 | 35.2 |
| It is unethical | 6 | 4.7 |
| *Reasons for not considering it illegal (n = 176)* | | |
| If the patient would benefit from it | 26 | 14.8 |
| Information on drug leaflet may be inadequate | 51 | 29.0 |
| Since effectiveness has been confirmed | 88 | 50.0 |
| Not aware of any legal limitation | 11 | .6.2 |

Table 6 shows the prescriptive attitude of the respondents towards the use of OCs and IUCD as emergency contraceptives. While 64.5% of the respondents are aware that these methods can be used for emergency contraception, remarkably, only 42.1% would recommend or prescribe them for that purpose despite lack of such use in the manufacturer's drug leaflets. Those that would not do so cited such reasons as risk to the patient, lack of effectiveness and avoidance of litigation.

**Table 6:** Prescriptive attitudes of respondents towards emergency contraception

| Issues | Respondents Number | Percent |
|---|---|---|
| *Awareness of OCs and IUCDs for Emergency Contraception (n = 363)* | | |
| Yes | 234 | 64.5 |
| No | 109 | 30.0 |
| No response | 20 | 5.5 |
| *Would you prescribe OCs & IUCDs for Emergency Contraception despite lack of such use in manufacturers' labels? (n = 363)* | | |
| Yes | 153 | 42.1 |
| No | 180 | 49.6 |
| No response | 30 | 8.3 |
| *Reasons for prescribing OCs & IUCDs as Emergency Contraceptives (n =147)* | | |
| Have been proven to be effective | 129 | 87.8 |
| May benefit the patient | 18 | 12.2 |
| *Reasons for not prescribing OCs & IUCDs as Emergency Contraceptives (n = 154)* | | |
| May be risky to the patient | 68 | 44.2 |
| May be ineffective | 43 | 27.9 |
| Avoidance of litigation | 23 | 14.9 |
| Unaware of their effectiveness | 20 | 13.0 |

*In-depth interviews on regulatory aspects of ECPs*

It was apparent from the in-depth interviews conducted with the two regulatory agencies responsible for drug control in Nigeria, NAFDAC and Pharmacy Council of Nigeria (PCN), that there are no laws specific to drugs currently dispensed as methods of family planning in the country. Drug dispensing laws in Nigeria relate to all drugs. The two agencies have specific roles but interact with one another. While NAFDAC is solely responsible for licensing drugs for use in the country, PCN controls the registration of pharmacists and pharmaceutical outlets. Only pharmacists are authorised to register drugs with NAFDAC.

The "Drugs and Related Products (Registration, etc. ) Decree No. 19, 1993" prohibits the manufacture, importation, exportation, advertisement, sale or distribution of any unregistered drugs, drug products, cosmetics or medical devices in Nigeria (Section 1 (1) [13]. However, an exception to this prohibition is provided in Section 1 (2) whereby NAFDAC is authorised to grant permits in respect of the importation and manufacture of samples of drugs, drug products, cosmetics or medical devices for the purpose of registration or clinical trial, and the importation or manufacture should comply with conditions contained in the permits. Such drugs, drug products or medical devices must be registered with NAFDAC. Furthermore, this Decree provides that the process of registering the drug may require the applicant to supply all information deemed necessary by the Agency (Section 2 (3) [14,15]. The validity of every registered drug is five years and is subject to renewal. Notification of such registered drugs, drug products or medical devices is to be published in the Gazette. This law also makes provision in respect of offences committed by individuals and corporate bodies. Thus, before any OC can be imported, manufactured, assembled, stored or used, it should be registered in compliance with the provisions of the decree.

Regarding the use of OCs as ECPs despite lack of indication for such use in the manufacturers' drug information leaflets, PCN is of the opinion that "using a drug for indications not stated on the drug information leaflet is, technically, drug abuse." It stated further that the current practice whereby OCs are dispensed in FP clinics without involving pharmacists is unethical.

NAFDAC offers guidelines to pharmaceutical companies planning to market drugs in Nigeria. It also monitors the flow of drugs marketed in the country. The Agency scrutinises the information provided in manufacturers' information leaflets to the extent that all necessary information must be provided to it before approving the use or sales of the drug. Therefore, all indications for a drug must be registered with the Agency. In its opinion, NAFDAC states that using a drug for indications not stated on the drug information leaflets is "illegal"! Therefore, to use the currently available OCs as ECPs, the drugs must be re-registered for emergency use. Furthermore, re-packaging will necessitate re-registration and must be conducted according to the Agency's guidelines.

**Discussion**

Emergency contraception is a recent nomenclature for an old method, otherwise known variously as post-coital or morning-after pills [15]. However, most physicians and other healthcare providers are not aware of this mere change in nomenclature. Emergency contraception has been found to be very safe and effective [2,16,17]. Previous studies on the knowledge and use of emergency contraception among Nigerians have reported a widespread lack of knowledge on how to use them, and where to obtain services [18,19]. Similarly, other surveys from outside Nigeria have reported inadequate knowledge of emergency contraception by various groups of potential users [20,21]. In a study among students with previous clandestine abortions in Southwest Nigeria, results showed that only 31.1% and 10.2% of the respondents, respectively, knew about emergency contraceptive pills (ECP) and IUCD [19]. Unprotected sexual activity, especially among adolescents, leading to unwanted pregnancies and illegal abortion is posing increasingly serious health problems. Probably, if emergency contraception were well known and generally available in Nigeria, many women who experience unprotected intercourse would use it rather than resort to abortion.

Except Postinor®, no other drug information leaflet (for conventional OCs encountered) stated any instruction that connoted emergency use. Existing guidelines require that a manufacturer or marketer of a product re-register a drug for every new indication or use, if it was not contained in the initial application. Oral contraceptive pills (OCs) and intra-uterine contraceptive devices (IUCDs) are freely available in the Nigerian market. There is no written legal or institutional restriction to their use, solely for the purpose of family planning. Although some of the healthcare providers are aware of the potential of

the OCs and IUCDs being used for emergency contraception, much fewer of the number will actually prescribe or recommend them for the same purpose. It would appear proper that, OCs need to be re-registered, and appropriately re-labelled for them to be properly marketed for potential use as ECPs.

Our study revealed that health care providers do not always read the drug information leaflets for drugs they recommend or prescribe. Therefore, the information contained therein is unlikely to consistently affect prescribing practices. Our sample of respondents appears to be on the low side in terms of contraceptive prescription and/or recommendation. This is accountable for, by the fact that, it is not a homogeneous specialty group such as Gynaecologists and Family Planning Nurse practitioners. However, this pattern is probably indicative of the pattern in an urban, cross-mixed contracepting population. The mix of respondents is probably representative of what obtains for Nigerian healthcare providers as a whole. As can be seen from the questionnaire survey, oral contraceptive pills are prescribed regularly by the respondents. One would expect that it would be practically easier therefore to expand the prescription spectrum to encompass ECPs. The practice of prescribing drugs for indications other than stated on labels is not new at least on the international scene. It is also very likely that questionnaire-surveyed healthcare providers in Nigeria, would or have actually prescribed drugs for indications not stated, OCs inclusive. Afterall, most gynaecologists unassumedly prescribe oral contraceptive pills to provoke a hormone-withdrawal bleeding for amenorrheic states except pregnancy, to stimulate endometrial re-growth in uterine synechiae, to postpone menstruation to when convenient and to promote the development of secondary sexual characteristics in females with ovarian agenesis. All of these indications are not stated on all drug information leaflets.

Does the physician need to disclose to the patient that the ailment being treated with the drug prescribed for her is not recommended by the manufacturer? Regarding the issue of disclosure of information by professionals in the field of health pertaining to ensuring that right of the patient to know and to make right choices affecting the protection of their state of health, the Court in Canterbury and Spense [22] observed as follows: "In duty to disclose cases, the focus of attention is more properly on the nature and content of the physician's divulgence than the patient's understanding and consent. Adequate disclosure and informed consent are, of course, two sides of the same coin. The former is a *sine qua non* of the latter. But the vital enquiry on duty to disclose relates to the physician's performance of an obligation while one of the difficulties with analysis in terms of informed consent is its tendency to imply that what is decisive is the degree of the patient's comprehension." The physician fulfils his obligation when he supplies information required in a manner aimed at ensuring keen appreciation by the patient through the provision of information that is adequate to meet his/her situation. The information should be couched in such a way that the average patient could understand. For example, the patient ought to understand that having used a certain drug, he may recover, or that the best she can expect is a relief of her discomfort, or that there may be harmful side effects of the treatment. In other words, what renders the patient competent to make decisions is the fact that he or she can understand, from the information given, the likely personal impact of his or her choice. McLean [23] observes that according to autonomy theorists, failure of the physician to ensure the patient's understanding would result in the possibility of a law suit against him solely because of any incapacity. She further highlights another problem may arise as being that of "Rational Choice." However, it is not clear whether the making of a rational decision is the delimitation of the patient's rights to autonomy or self-determination. It is, for example, believed that a substantial proportion of illnesses is self-limiting [23]. Many common reasons for consultations are believed to be susceptible to environment or other changes.

What are the implications of using OCs as EC to the manufacturer and the physician since this is not stated as an indication in the drug leaflet? Under the Law of Contract, the Caveat Emptor rule applies in transactions of the commercial nature whereby the burden is placed on the buyer to beware and cautious of the types of good being purchased. The phrase "type of goods" here connotes the nature, quality, quantity and fitness for purpose of the product being negotiated for. The buyer therefore undertakes the risk to a certain extent in accepting the goods as offered by the seller. The seller, on the other hand, is duty bound under the Sale of Goods Act (1893) [24] to ensure that the goods being offered for sale at a given price are delivered as required in accordance with expressed or implied terms of the contract. Such implied terms may pertain to title, description, quality, quantity, time and place of delivery of the goods. Thus, where a drug is deemed or ascertained to be unregistered, contrary to a given law requiring registration of same, it is apparent that, the seller has no right to lawfully sell or contract to sell the drug in question. Another legal obligation of the seller of goods is the requirement that the goods being offered for sale should correspond with the description given or presented in a prescription form or order, catalogue or advertisement. This requirement is based on the fact that it is important that the goods being sold should be properly identified or ascertained as being appropriate to the demands of the buyer. The word "description" covers a wide variety of matters that include statements as to quality, weight, ingredients and packing [24]. It is also required in law that the goods should be fit for the purpose or purposes for which it has been purchased. Drugs sold should also correspond with any samples offered in terms of quality and a reasonable opportunity for comparison with the bulk of drugs offered for sales should be given.

The breach of an expressed or implied contract may result in a remedy for damages, i.e., a monetary assessment of losses incurred directly or indirectly as a result of the breach. Another remedy is presented by the right afforded the buyer to reject the goods and thereby bring the contract to an end. Where goods have passed through several intermediaries or hands, the Sale of Goods Act merely provides remedies against the immediate seller and not the previous owners or manufacturers [24]. The buyer's lawful right of action may lie only in tort upon proof of the manufacturer's negligence where it is unconscionable to sue the immediate seller. A major problem facing potential litigants, the consumers of drugs, for example, is the difficulty of ascertaining or proving the carelessness of the manufacturer. A recourse has often been made by the court to the application of the maxim "*res ipsa loquitor,*" that is, "the act speaks for itself" [25]. By the application of this maxim, onus or burden of proof is placed on the manufacturer directly rather than on the innocent purchaser or consumer. It is

therefore required that the former should discharge this burden of liability placed on them by proving that they have not been negligent in the production, distribution, packaging or sales of the product. The user or consumer can therefore institute a negligence action to establish liability on the part of the manufacturer, distributor, or supplier of an unregistered drug which has proved defective to the well-being of the former. However, in some legal jurisdictions, liability is strict, obliviating the need to prove causation for the purpose of obtaining compensation.

Where a physician prescribes OCs for uses not stated on the drug information leaflet, such may ordinarily be presumed not to be an approved or lawful use. On the other hand, it may be proffered that where the purpose or motive for using the said drug is for the preservation of life in consonance with constitutional provisions which guarantee right to life (Section 33 (1) [14,15,26] for every citizen, such contingency use should not be regarded as being unlawful. However, upon an in-depth consideration of pertinent legislation dealing with or touching upon salient aspects of prescribing or marketing OCs as ECPs, it is imperative that health care providers should operate within the defined ambit of the law. They should at all times consider and pursue actions that are objectively considered to be in "the best interests of the ultimate stakeholders", that is the clients, as well as the collective interest of the Nigerian society in the quest for sustainable development.

It is also necessary for all interested groups, namely, women, medical/health science personnel, government, non-governmental organisations and private sector manufacturers to determine whether in the light of the legal exposition above stated, Nigerian Law and Policy has the tendency to assist or otherwise compound legal access to and provision of emergency contraception. Specific policy statement should be made to address the issue. The lacuna in the law should be filled, for example, by making provision to control and regulate such use. In addition, the law should contain an omnibus provision or general clause which allows for the use of OCs as ECPs in contingency situations that are deemed appropriate by the law in public interest and for common good.

**Acknowledgements**

We acknowledge the contributions of the following individuals to the success of the questionnaire survey: Professor O. K. Ogedengbe, Professor J. A. M. Otubu and Dr. A. Sule-Odu. We also thank Dr. Bawa Abubakar and Mrs. C. M. Makanjuola of National Agency for Food and Drug Administration and Control, Lagos. The study was funded by the Ford Foundation through the Society for Family Health, Lagos, Nigeria.

**References**

1. Fasoli M, Parazzini F, Cecchetti G, La Vecchia C. post-cital contraception. Contraception 1989; 39: 459-68.
2. Trussel J, Stewart F. The effectiveness of pot-coital contraception. Family Planning Perspectives 1992; 24: 262-264.
3. Robinson TE, Metcalf-Whitlaker M, Rivera R. Introducing Emergency Contraceptive services: Communications strategies and the Role of Women's Health Advocates. International Family Planning Perspectives 1996; 22(2): 71-76.
4. Silvestrel L, Bouali Y, Ulmann A. Post-coital contraception: myth or reality? Lancet 1991; 338: 39-41.
5. Van Santen MR, Haspels AA. Interception III: Postcoital luteal contraception by an antiprogestogen (mifepristone RU 486) in 62 women and failure of mifepristone as a monthly contraceptive. Contraception 1987; 35: 425-438.
6. Van Look PFA. (1987). Post-coital contraception: a cover up story. In: Diczfalusy E., Bygedeman M. (Eds.). Serono Symposia. New York: Raven Press 1987; 36: 29-42.
7. Van Look PFA, Von Hertzen H. Emergency contraception. British Medical Bulletin 1993; 49: 158 – 170.
8. Smith BH, Gurney EM, Aboulela L, Templeton A. Emergency contraception: a survey of women's knowledge and attitudes. British J Obstet and Gynaecol 1996; 103: 1109-1116.
9. Haspels AA. Post-coital contraception. Lancet 1991; 338: 508.
10. Needle RH. The relationship between first sexual intercourse and ways of handling contraception among college students. Journal of Am Coll Health 1975; 24: 106-111.
11. Noteloitz MB, Bard DS. Conjugated estrogen as a post-ovulatory interceptive. Contraception 1978; 17: 443-54.
12. Tadiar FM, Robinson TE. Legal, Ethical and Regulatory Aspects of Introducing Emergency Contraception in the Philippines. International Family Planning Perspectives 1996; 22(2): 76-80.
13. Federal Government of Nigeria. Drugs and Related Products (Regulation, e.t.c) Decree Number 15 of 1993.
14. Federal Government of Nigeria. National Agency for Food and Drug Administration and Control Decree Number 15 of 1993.
15. Ellerton C. History and Efficacy of Emergency Contraception: Beyond Coca-Cola. International Family Planning Perspectives 1996; 22(2): 71-76.
16. Web AMC, Russel J, Elstein M. Comparison of Yuzpe regimen, danazol and mifepristone (RU 486) in oral and post-coital contraception. Brit Med Journal 1992; 305: 927-931.
17. World Health Organization Task Force on Post-ovulatory Methods of Fertility regulation. Randomised controlled trial of levonorgestrel versus Yuzpe regimen of combined oral contraception for emergency contraception. Lancet 1998; 352: 9126: 428-433.
18. Bako, AU, Knowledge and use of emergency contraception by Nigerian undergraduates. J Obstet Gynaecol 1998; 18: 151-153.
19. Arowojolu AO, Adekunle AO. Knowledge and practice of emergency contraception among Nigerian youths. Int J Obstet Gynaecol 1999; 19: 632-636.
20. Gooder P. Knowledge of emergency contraception among men and women in the general population and women seeking abortion. British Journal of Family of Planning 1996; 22: 84-86.

21. Smith BH, Gurney EM, Aboulela L, Templeton A. Emergency contraception: a survey of women's knowledge and attitudes. British J of Obstet Gynaecol 1996; 103: 1109-1116.
22. 464 F2d. 772 (1972).
23. Mclean SAM. A patient's right to know – Information disclosure, the Doctor and the Law. Dartmouth Publishers, 1989.
24. Marsh SB, Soulsby J. Legality of selling and buying unregistered drugs: Sale and supply of goods. In: Thornes S (ed.) Business Law. Chlterham: McGraw Hill Publishers, 1994; 185–191.
25. Marsh SB, Soulsby J. Legality of selling and buying unregistered drugs: Negligence. In: Thornes S. (ed). Business Law. Chelterham: McGraw Hill Publishers, 1994; 90-96.
26. Federal Government of Nigeria. The Constitution of the Federal Republic of Nigeria, 1999.