

PHUTURE

IPSF EDUCATION SUPPLEMENT

14th Issue June 2007



ETHICS



Message From IPSF

Dear Reader,

The International Pharmaceutical Students' Federation (IPSF) is pleased to present you this year's *Phuture* supplement on "Ethics" – the science of morals, rights and duty.

A profession is identified from an occupation by specialised knowledge, licensure, self-regulation and peer discipline, as well as adherence to conduct and standards that exceed legal requirements. As such, and by virtue of dealing with human lives in the course of their work, ethics are of utmost relevance and importance to all healthcare professionals, including pharmacists. The purpose of ethics in healthcare is to promote and protect the wellbeing and welfare of those whose health status is or is potentially at risk by ensuring that the best decisions are undertaken by the patients, their associates and attending healthcare professionals.

Pharmacy is represented by pharmacy practitioners and pharmaceutical scientists who are all responsible for patients and to one another in the course of their work. Situations of accountability and integrity, professional responsibility and obligation, confidentiality and privacy are commonly encountered. Furthermore, as globalisation and cross-border mobility increases, pharmacists will be required to recognise and respect culture-specific ethics too.

This issue features a range of articles by authors from various sectors of the pharmacy profession as well as from the United Nations. We thank them for their kind contributions. While it is impossible to fully address ethics in a short supplementary publication, we hope that the information and ideas on the following pages will garner notice and stimulate debates in all current and future science and healthcare practitioners.

Have a pleasant read.

Zhining Goh
IPSF Chairperson of Education and Practice 2006-07



Pharmacist Code of Ethics - A Comparison of the American, British and Japanese Systems

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A code of ethics is a formal statement of values on certain ethical and professional issues. Ethical decision making is the process of recognising a problem, identifying possible solutions, choosing one and taking responsibility for the decision made. In the pharmaceutical profession many questions can occur that only have one obvious solution, while there are occasions when there is no right and wrong decisions and more solutions can be justifiable. A code of ethics is prepared to serve as a basis for ethical decision making in the conduct of professional work and as a basis for judging a complaint of professional misconduct.

Here the Code of Ethics for Pharmacists adopted by the American Pharmacists Association membership on October 27 1994, the Japanese Code of Ethics for Pharmacists accepted on October 24 1997 by the Japan Pharmaceutical Association and the Code of Ethics and Standards of the Royal Pharmaceutical Society of Great Britain updated on May 24 2006 are reviewed and compared to obtain an international view on ethical practices.

Role of pharmacists

The role of pharmacists is seen differently in the three countries, but the documents share a common basic view that pharmacists are health professionals whose responsibility is to help patients with making the best use of medications, promote good health and life, contribute to improving the level of medical care and ensure the safety of patients and the public.

Relationship with patients

The relationship with patients is a key issue in the professional life of a pharmacist. It is essential that pharmacists maintain the public's trust by respecting the autonomy and dignity of each patient, respecting their rights to participate in decisions about their care and providing information in a way in which it can be understood. Pharmacists also have to be polite and treat all matters in a private and confidential manner. Confidential information includes personal details and both prescribed and non-prescribed medication.

In all cases, a pharmacist has to respect personal and cultural differences among patients. Pharmacists are also encouraged to contribute to the promotion of healthy lifestyles and hygiene.

Responsibilities

The main responsibility of pharmacists is to provide healthcare services in a safe and effective way. Other responsibilities include maintaining high and up to date standards of knowledge, skills, performance and abilities as new medications, devices, and technologies become available and as health information advances. Pharmacists should make a constant effort to assimilate the latest progress achieved in the field of pharmaceutical and medical sciences and make a contribution toward welfare of the mankind. In the United Kingdom practising pharmacists are expected to maintain records of their continuing professional development as an ethical obligation.

Pharmacists work as members of a multidisciplinary healthcare team; therefore they should always cooperate fully with fellow pharmacists as well as with other members of the medical profession in order to benefit the patient in all areas of medicine, public health and welfare. When appropriate, a pharmacist should ask for the consultation of colleagues or other health professionals. It should be acknowl-



edged that colleagues and other health professionals may differ in the beliefs and values they apply to the care of the patient.

While focusing on individual patients, pharmacists should also work towards making contributions to society at large. At times, obligations of a pharmacist may extend beyond the individual. In these situations, the pharmacist should recognise the responsibilities that accompany these situations and act accordingly. In emergencies, pharmacists must consider using their rights to make emergency supplies of medicines whenever a patient has an urgent need for a medicine.

Pharmacists should always remain autonomous and free from influence. They should avoid discriminatory practices, behaviour or work conditions that impair professional judgement and actions that compromise dedication to the best interests of patients.

Pharmacists have to be familiar with and follow all regulations and codes of practices pertaining to their professional duties including all pharmaceutical, medical and health insurance law and any other statutory requirements applicable to their sphere of practice.

As a basic professional and personal responsibility, pharmacists should never abuse or undermine public confidence in the profession. They should never engage in any behaviour or activity likely to bring the profession into disrepute or that would result in the loss of the trust or respect placed in them.

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Ethics, Conscientious Objection and the Future of Pharmacy

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Ethical concerns in pharmacy have never been more relevant, both for those practising and students hoping to enter the profession. Current debates about pharmacists' participation in physician assisted suicide (PAS), abortion and the supply of emergency hormonal contraception (EHC) have shown that pharmacists cannot ignore their role in these significant developments in healthcare. One way in which healthcare professionals try to resolve ethically sensitive issues is to rely upon appeals to conscience and their recognition in conscience clauses in professional codes and legislation.

In this paper I want to consider whether pharmacists are justified in conscientiously objecting to certain practices in pharmacy work. Drawing upon the example of pharmacists' conscientious objection to the supply of EHC, I argue that despite the practical solutions advanced, conscientious objection may be problematic not only because it relies upon an external liberal respect for the autonomy of individuals' beliefs rather than any internal ethical justification but also because pharmacists have professional responsibilities and because pharmacy services are finite in practice. I argue that pharmacists need to consider more fundamental ethical justification but that this may not presently be the case since empirical research suggests pharmacists are unwilling to take ethical responsibility and to identify and discuss ethical issues openly. This is especially problematic since medical advances may lead to more ethical concerns in pharmacy in the future and for pharmacy students, this means considering carefully whether they can enter a profession undertaking potentially ethically sensitive practices and whether they can develop the necessary ethical skills to identify, discuss and reason about ethical issues.

Conscientious objection represents a way in which healthcare professionals try to deal with ethically and religiously sensitive issues and there is recognition in pharmacy ethical codes and also legislation, such as the UK and USA for example, that pharmacists need not participate in activities that would con-

flict with their consciences. What is problematic for pharmacy, however, is that conscientious objection has been questioned and argued to deny patients medicines and treatment that they require^{1,2}. This has been particularly evident in USA in relation to EHC, where some states have enacted further legislation that makes it illegal to refuse to supply EHC and pharmacists have reportedly lost their jobs for refusing to supply EHC³. Academic pharmacy responses^{4,5} have often been pragmatic and have noted that conscientious objection should be permitted but that pharmacists must ensure that patients receive the necessary information about obtaining the medicine or service elsewhere. Indeed, this is often drafted into formal clauses in codes and legislation but despite such pragmatic, legal and codified solutions, there remain a number of concerns about conscientious objection.

Firstly, it appears to be justified only when there would be another pharmacist available to offer the service but this might not always be the case. In many healthcare systems – even those of relatively prosperous nations – it may not always be possible to find another pharmacy in a timely and convenient manner, especially in rural areas, in the evenings or at weekends. Secondly, even referring a patient or having to give advice may be more than some pharmacists are prepared to do⁶. Thirdly, conscience clauses may actually carry little ethical justification since their authority stems not necessarily from any intrinsic ethical argument but rather from an extrinsic liberal tolerance of autonomous beliefs. Fourthly, conscientious objection ignores rival values in professional responsibilities since although an individual's autonomous beliefs are rightly tolerated in liberal societies, if that individual also undertakes a professional role, then they must accept the societal responsibilities of that professional role also. Relating this point to medicine, Savulescu argues that if a doctor cannot offer a medical service that is recognised as being legal and beneficial then they should not be a doctor: a doctor's conscience should be accommodated, but only if there is no harm to the patient¹.

However, in arguing that conscientious objection is not a sustainable reason for pharmacists' non-supply, this does not mean that ethical values and reasoning do not enter into pharmacy practices. It is essential that pharmacists engage and reflect upon the values and ethical concerns in their work but not necessarily resort to the potentially empty and challengeable claims of conscientious objection. Although pharmacists' consciences represent attempts to reconcile personal beliefs and professional practices and can understandably lead to guilt or remorse and should not be ignored, they may not amount to considered ethical reasoning and justification⁷ and this reflects wider concerns in pharmacy about ethical understanding and responsibility.

Research suggests that pharmacists may be unwilling to either reflect upon or accept responsibility for ethically sensitive issues such as PAS⁸ and may be ethically passive and inattentive to ethical concerns in their work⁶. These findings suggest that far more needs to be done to raise the profile of ethical issues in pharmacy, to inculcate via pharmacy training the need for both practising pharmacists and students to debate and reflect upon ethical issues in pharmacy and healthcare more generally. This will not offer an easy answer to the ethical demands of medical advances such as stem cell research and genetic medicine as well as present issues such as EHC, abortion and PAS but may provide a useful starting point in encouraging open, unbiased debate. Given the difficulties of conscientious objection, pharmacy students must therefore consider whether they want to enter into not only an ethically challenging profession but also one that requires them to debate and justify their ethical beliefs and actions.

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Ethics in the Conduct of Clinical Trials and the Publication of Clinical Trial Information – A Pharmaceutical Industry Perspective

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Clinical trials are governed by ethical and legal codes, which reflect more than half a century of discussion amongst medical, legal and ethics specialists. The first set of ethical guidelines for research on humans, was developed in response to the Nuremberg Trials of Nazi doctors who performed barbaric experiments on prisoners during World War II. Known as “The Nuremberg Code”, it was adopted by the United Nations General Assembly in 1948, and requires that participants in trials be volunteers and that they should understand the benefits and risks involved (“informed consent”). The World Medical Association’s “Declaration of Helsinki” adapts the Nuremberg Code to medical research with a therapeutic intent, provides guidelines for trial protocol issues (such comparison of a new treatment with an existing one, or against placebo) and calls for review of trial protocols by independent ethics committees. It has been endorsed, implicitly by some parties and explicitly by others as a cornerstone of other ethical guidelines, national and international.

The thalidomide tragedy in the 1960s prompted a fundamental review of the conduct of clinical trials, in which the industry has collaborated closely with regulatory authorities to develop and to implement international, European and national Good Clinical Practice (GCP) standards. As a result, the US Food and Drug Administration (FDA) published the first GCP standards in 1977. The International Conference on Harmonization (ICH) - which brings together industry and leading regulatory authorities - subsequently adopted international Guidelines for GCP in 1996, drawing on best practices from various countries and input from the World Health Organization (WHO).

ICH GCP facilitates mutual acceptance of clinical data by the regulatory authorities of the European Union, Japan and the United States, and provides an international standard for the design, conduct, recording and reporting of clinical research involving human participants. Compliance with this standard provides public assurance that the rights, safety and well-being of human participants are protected, as required by the Declaration of Helsinki. ICH GCP has been incorporated in national law in major industrialized countries and several emerging countries involved in global clinical development program, and it is regarded by pharmaceutical companies as the “gold standard” for the conduct of clinical trials.

The ICH GCP guidelines, the Declaration of Helsinki and the Nuremberg Code provide companies and researchers with a framework for addressing the ethical issues related to trial participation, design and conduct. Nevertheless, other issues with an ethical dimension have emerged in relation with clinical trials, notably the public registration of on-going clinical trials and the publication of results of completed trials.

The research-based pharmaceutical industry made a commitment in January 2005 to enhance clinical trial transparency significantly through the public registration of new and ongoing clinical trials on a publicly accessible internet registry site, within 21 days of the start of enrolment of patients. In particular, this includes information which would allow interested physicians and patients to enquire about enrollment. Companies also committed to publish on a publicly accessible internet site summary results of any such trial within one year of the first approval anywhere in the world of the medicine which was the object of the trial.

As a further, practical measure to help physicians and patients find information on trials, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA - the global body representing the research-based pharmaceutical industry) has created the IFPMA Clinical Trials Portal (www.ifpma.org/clinicaltrials). This is a highly specialized and easy to use search engine which provides the general public, as well as patients and researchers, with a “one-stop-shop” where they can search for all available registry entries and summary reports of clinical trials undertaken by R&D based pharma-

ceutical companies.

The Clinical Trials Portal (CTP) allows users to search for trials satisfying multiple search criteria, allowing a search for, say, all trials relating to a specific disease in a specific country. It includes software which suggests synonyms for medical conditions terms, to help users who are unfamiliar with medical terminology, and allows criteria expressed in English, French, German, Japanese and Spanish. If a user enters a particular search criterion in one of those languages (e.g. cancro), the portal will automatically search not only for that term, but also for equivalent terms in the other four languages (e.g. Krebs, cancro, cancer and 癌). Further developments to the portal will include a facility to allow users to request an alert whenever a new trial is added in a specified therapeutic field.

Public demands relating to the ethical conduct of clinical trials of medicines, as well as dissemination of information about on-going and completed trials, have evolved over time and will doubtless continue to do so. In the full knowledge that its ability to function depends critically on public confidence, the research-based pharmaceutical industry is taking the lead in addressing such public concerns in a systematic and transparent way.

The Study of Bioethics in Medicine and Pharmacy Universities

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In 1971, the oncologist Van Renselaer Potter (1911-2001) introduced "bioethics" in his book "Bioethics: Bridge to the Future", designating it as "a new discipline which combines biological knowledge with human values"¹. Biological and medical disciplines have come to know unexpected accomplishments in the past decades, directly affecting human health and life hugely. Reproduction, birth, life and death, all considered immutable before, are now being transformed through contemporary biology and medicine. Progress in the biomedical sciences and biotechnologies have offered mankind real possibilities of controlling procreation, heredity, thought and behaviour. They open new fields of action for health workers, and multiple interventions are now possible in the area of life and death - in-vitro fertilisation, surrogate mothers, genetic modification, stem cell research, organ and tissue transplantation, foetal experiments, medical assisted suicide etc - where, a few decades ago, Nature almighty was the main actor.

At the same time, the danger of considering medicine as just a technical science and of transforming the human being from a subject to a mere object, sometimes for manipulation in biomedical research and health care, create multiple dilemmas and complicated situations of choice and decision in fields which before were out of comprehension and action. This raises the issue of ethical values which should help to elucidate and solve the ethical dilemmas created by biomedical progress, as the elaboration of a set of principles and moral criteria to help healthcare staff make the right decisions in the new situations. Bioethics also aims to reconsider the traditional ethical precepts and norms and to adapt them to "novel" and complex situations which often defy the basis of general moral rules. For example, the respect for life, dignity and human being and the refusal to "instrumentalise" the human body deny of "instrumented" human bodies, must be looked from another perspective in the conditions of artificial life prolongation, organ retrieval etc. Which is preferred - a dignified death or a life that has no dignity, artificially prolonged and reduced to a simple vegetative state?

Doctors nowadays must not only take into consideration clinical or technical issues when making treatment decisions, but also values, rights and responsibilities. Sometimes ethical dilemmas occur more frequently than the scientific and technical ones and medical staff must be prepared to deal with them. This is why the necessity of bioethics study was sustained by many national and international organisms such as UNESCO, The European Council and World Medical Association (WMA) etc. In 2005 the WMA Ethics



Manual was published with the main purpose of helping to “prepare medical students and physicians to better navigate through the many ethical challenges we face in our daily practice and find effective ways to **“put the patient first”**”². The appraisal of the moral aspects of biomedical decisions is made through a set of fundamental bioethical principles of bioethics - autonomy of the patient, beneficence, non-maleficence and justice³. These principles compose a frame of moral evaluation to aid healthcare professionals’ judgement.

Personal autonomy can be defined as the individual’s right to self-determination, expression and choice⁴. In bioethics this principle is enacted by the observance of some practices - obtaining informed consent, assessing patient competence and motivation for voluntary adherence to treatment or biomedical research, ensuring confidentiality etc. Some bioethicists believe that a healthcare system based on the principle of self-autonomy would stimulate the patients’ responsibility for their own health and uncover their desires for medical care and quality of life⁵.

Non-maleficence demands that healthcare professionals are forbidden to harm the patient under any circumstances, while beneficence entails that healthcare staff should participate actively part in the care and well being of the patient. Both principles must be taken into account in the process of taking care of a patient, and for this purpose professional competence is required - to ensure that healthcare professionals can render the help assured from their professions; to be certain that they offer individualised help for each patient not for the patients in general; and to evaluate correctly the risks involved in the interventions proposed..

Justice refers to the correct allocation of medical resources and everyone’s right to healthcare. This principle forbids the assignment of resources on ethically irrelevant criteria such as sex, nationality, religion and age. Ideal would be that medical care resources came to everyone that needs them. When this is impossible, their assignment should be made according to criteria such as the urgency or intensity of assistance needed.

Bioethical thinking is currently focused on issues generated by the biomedical progresses. Some scientific researchers warn that the usage of biotechnologies exposes humanity to the risk of losing their own biological nature⁶. Signaling such dangers, bioethics underlines that any attempt to reshape the normal human being must be stopped, and that we have to obey diversity, equality and human dignity. Hence bioethics must be studied at universities so that it can become a guide to conscience and professional competence for all health care workers: doctors, pharmacists, biologists and others.

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UNESCO and Bioethics

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The United Nations Educational, Scientific and Cultural Organization (UNESCO) is the only UN agency with specific responsibilities for scientific research. The challenge is to promote scientific collaboration among the peoples of the world in order to advance the objectives of international peace and of the common welfare of humankind. It also ensures that the advances of science and technology will take place within an ethical framework. In 1993, the Member States decided to establish the UNESCO International Bioethics Committee, the first global bioethics body. This has been the start of an explicit program in the ethics of science and technology, in particular bioethics. In 2002 ethics has been earmarked as one of the five principal priorities of UNESCO.

Many countries have a limited infrastructure in bioethics, lacking expertise, educational programs, bioethics committees and legal frameworks. The global nature of science and technology implies the need for a global approach to bioethics. Member States have mandated UNESCO to set universal ethical benchmarks covering issues raised within the field of bioethics. They want to work together towards identifying basic principles and shared values regarding science, technology and health care. Standard-setting action in the field of bioethics has become a necessity that is felt throughout the world, often expressed by scientists and practitioners themselves, as well as by legislators, policy-makers and citizens. The desire to develop international frameworks is often articulated by the least developed countries that are in need of normative guidance and that want to have the certainty that ethical principles are formulated on a global level so that the same standards are used everywhere.

It was in this context that the Members States adopted, unanimously and by acclamation on 19 October 2005, *the Universal Declaration on Bioethics and Human Rights*. For the first time in the history of bioethics, all States of the international community are solemnly committed to respect and implement the basic principles of bioethics, set forth within a single text. Previous international declarations (e.g. *the Declaration of Helsinki*) have been adopted by professional organisations such as the World Medical Association.

Standard-setting is only the first step. The Declaration adopted will remain paperwork if its provisions are not taken into account by and in the Member States. It is therefore necessary to initiate activities of capacity-building.

i. The Global Ethics Observatory

In order to provide Member States with proper tools for reflection and appropriate means for coping with emerging ethical challenges in science and technology, the Global Ethics Observatory (www.unesco.org/shs/ethics/geobs) presents a system of five databases:

- a) experts in ethics,
- b) ethics institutions and committees,
- c) ethics teaching programs,
- d) legislation, and
- e) codes of conduct.

ii. The Ethics Education Programme

Ethics teaching varies greatly between regions and countries. As a first step, data on ethics teaching programs are collected (GEObs Database 3). Meetings of ethics teachers have been organized in Budapest, Moscow, Split, Muscat and Istanbul, resulting in 110 teaching program descriptions (including pharmacy ethics). Another activity is the development of a core curriculum in bioethics, based on the fundamental principles of *the Universal Declaration on Bioethics and Human Rights*. This curriculum will enhance the introduction of bioethics teaching in universities. Finally, a training course for ethics teaching is provided for young professionals and scientists who are interested in teaching ethics. In 2007, this course will take



place in Kenya, Slovak Republic and Saudi Arabia.

iii. Assisting Bioethics Committees project

UNESCO has initiated a program to support the establishment of national bioethics committees. Through a series of guidebooks, practical information is provided. Task forces of experts assist countries in setting up such committees and in providing training of committee members in working procedures and ethical analysis. The first activities have started in Gabon, Ghana, Jamaica, Madagascar, Malawi and Togo.

Although ethics of science and technology has always had an international dimension, nowadays many international organizations have programs and activities in this area. This illustrates that ethics, and bioethics in particular, has evolved from academic discipline into field of public debate and global policy making.

Ethics in Humanitarian Aid

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If there is any field where ethics should prevail, it is humanitarian aid. And yet, it is a field where there is most likely to be an ethical slippage. The subject is so vast that it cannot be covered in one article. We will at best address some of the issues that humanitarian actors are concerned about.

Why does humanitarian aid raise ethical concerns?

First of all, because association funds are insufficient to help all the people in need, so each humanitarian action involves ethical choices - why these victims and not those?

With the same amount of money, we can treat either ten people living with HIV/AIDS or 1,000 patients with malaria - who do we choose?

With the same amount of money, we can either provide emergency assistance to 200,000 victims of a disaster, or establish a sustainable supply system for health centres in a health region covering a population of 1,500,000 people who do not have access to essential medicines - who do we choose?

Does the neutrality of humanitarian aid organisations, which is essential for working in politically very sensitive areas, imply a refrain from giving testimony on possible violations of human rights? Should we shut up to be able to stay with the populations and treat them, or should we break the silence at the risk of not being allowed to work in the area anymore, and abandon the populations?

Are humanitarian aid organisations at risk of being instrumentalised and serving political interests?

Does humanitarian aid not tend to impose its rules in recipient countries without respecting the culture of the population, or impose its own culture, take the place of local professionals, compete with local companies? Ethics is primarily about respect for others, respect for their rights, dignity, culture, intelligence and ability to find suitable solutions to their problems.

Ethics has been the subject of many debates among humanitarian aid organisations. Fortunately, these continuously question the legitimacy of their own actions, because it is not enough to do good; we must do it well.

For Pharmaciens Sans Frontières Comité International (PSFCI), a Charter has been developed to minimise the "negative side-effects" of the actions of the international Non-Governmental Organisation. Its members are asked to:



- Respect the standards established by the beneficiary countries' Ministries of Health regarding health policies in general and good pharmacy practice in particular, as long as these policies and standards are within the boundaries of the principles and objectives of Pharmaciens Sans Frontières
- Use and deliver quality medications that conform to current standards or to the standards set by traditional pharmacopoeia as long as they meet the standards defined by the national legislation and by the recommendations of international health authorities
- Promote the use of essential generic medicines
- Provide for local and regional procurement of pharmaceutical products that adhere to the quality standards as defined by international authorities and by Pharmaciens Sans Frontières Comité International
- Abstain from dispensing or exporting medications that have been used and/or that were returned to the pharmacy, or that were distributed to medical health professionals as free samples
- Adapt their techniques and/or practices to the standards used by health professionals in the recipient countries
- Abstain from introducing medications or techniques which have not been sufficiently proven as effective
- Work with their partners in a timely fashion towards assuring the perpetuation of their actions and resulting in the best chances for success
- Respect the local traditions, cultures and existing social structures of the country where the field mission is taking place

Each programme is discussed and agreed upon by all partners and pre-studied by the Pharmaceutical Department of the association. They ensure that the World Health Organization (WHO) guidelines for drug donations and existing national pharmaceutical policies are followed, and analyse the impact of the action to be taken on the different elements of development of the country.

Ensuring the full respect of the beneficiaries of its programmes, Pharmaciens Sans Frontières Comité International deserves the full confidence of all its partners. The international pharmaceutical profession can boast about being represented with dignity by its humanitarian aid organisation.

For more information about the organisation's actions, please visit <http://www.psfci.org> . Do not hesitate to contact us and join our efforts to help the two billion people who still lack access to essential medicines. Together we can make the difference and bring pharmacists' contribution to a better world.



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