Journal of the CHAMBER of PHARMACISTS
APRIL 1987 NO. 15

Matricaria chamomille.

THE PHARMACIST

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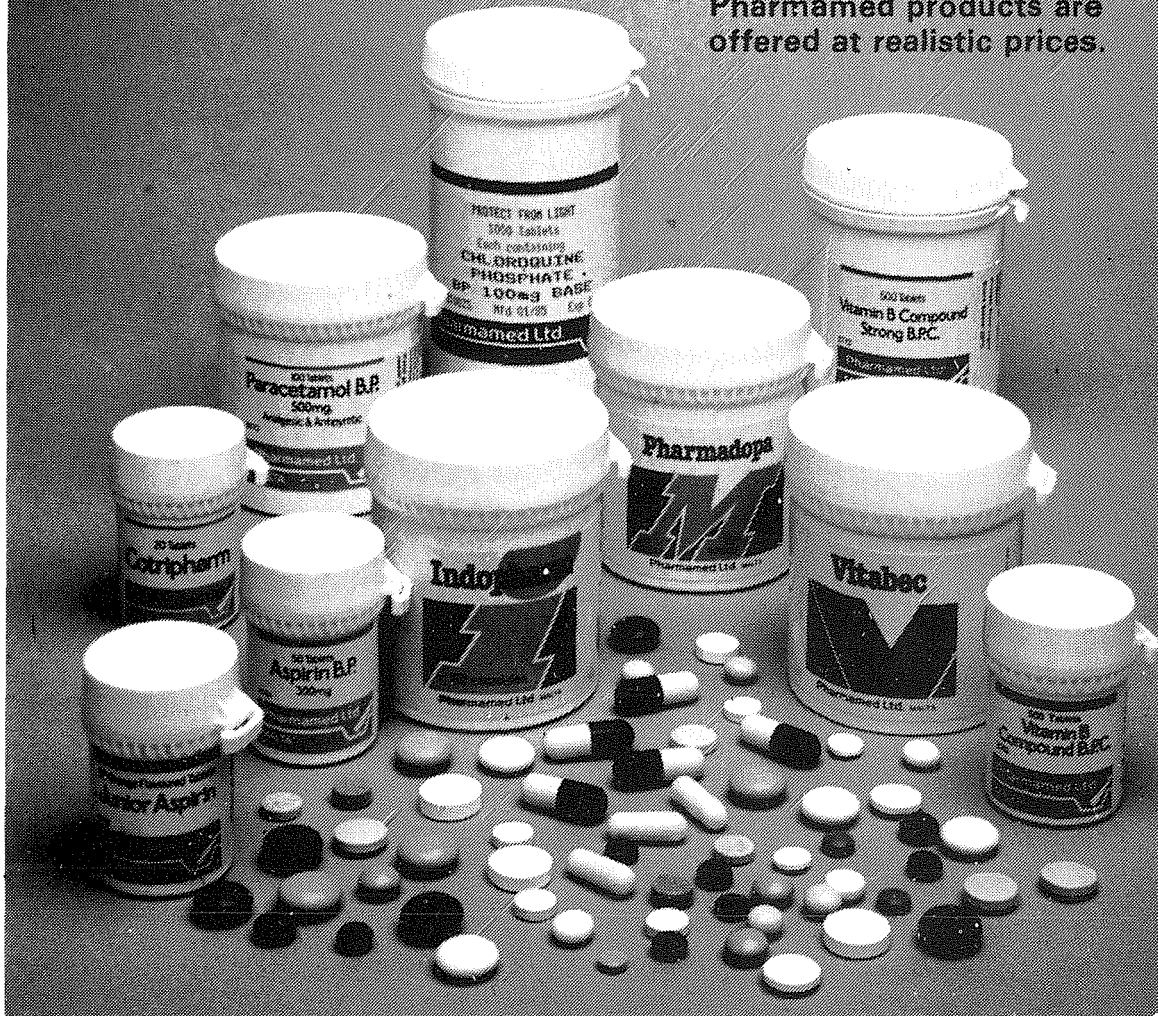

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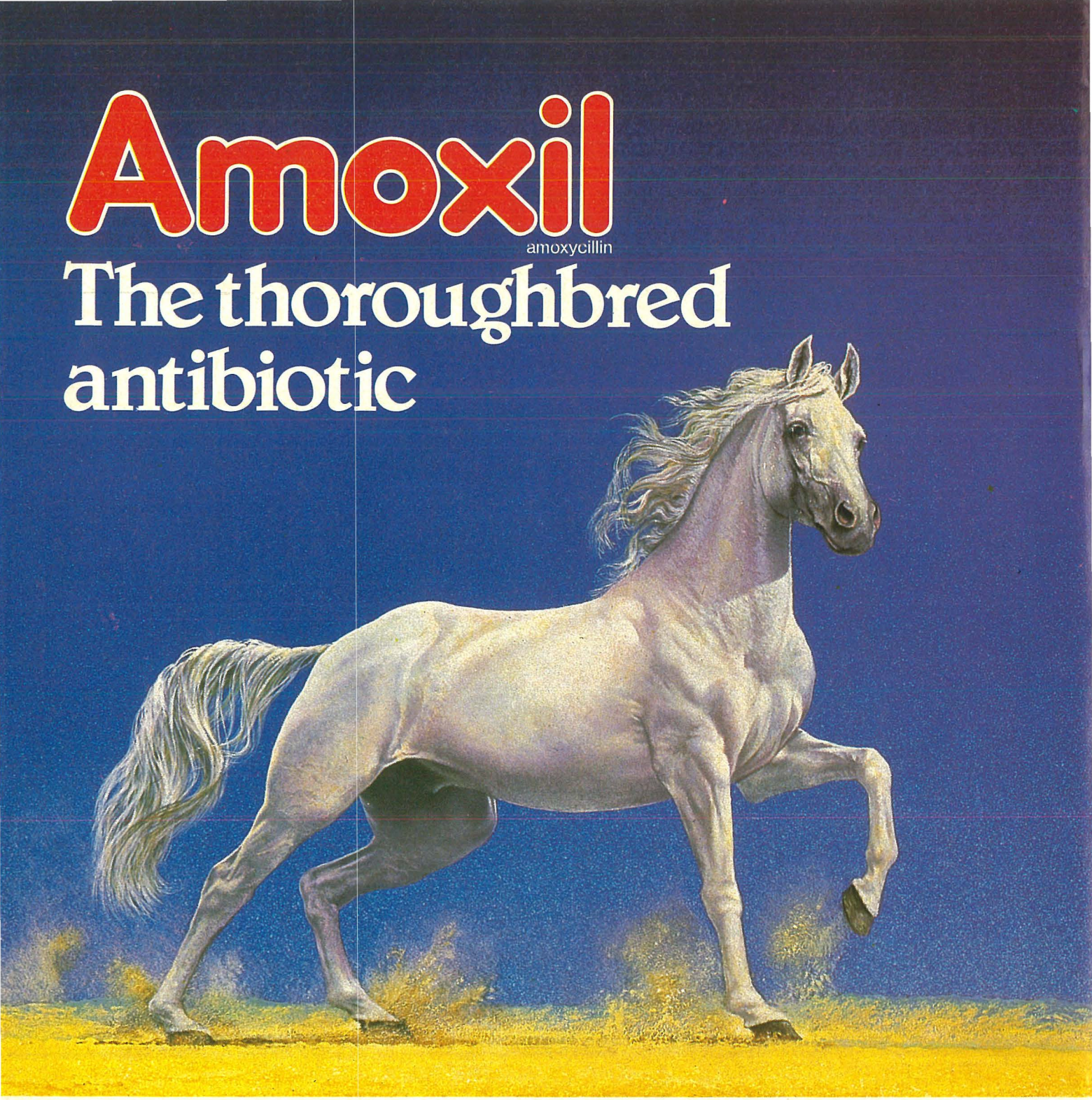
Amoxil

amoxycillin

The thoroughbred antibiotic



Prescribing Information

AMOXIL is a broad spectrum antibiotic suitable for a wide range of infections caused by susceptible organisms.

Indications
Respiratory, ENT, genito-urinary and skin and soft tissue infections.

Dosage
Children: Oral and injectable – up to 2 years: 62.5mg-125mg every 8 hours. 2-10 years: 125mg-250mg every 8 hours. Based on bodyweight (including neonates) 35-100mg/kg/day. Adults: Oral – 250mg-500mg every 8 hours. Injectable – I.M. 250-500mg every 8 hours or more frequently if necessary. I.V. 500mg 2g every 4 6 hours. (Doses in excess of 1g should be given by infusion over 30 minutes).

Presentations
Capsules: maroon and gold capsules, each containing 250mg or 500mg amoxycillin.
Syrup: 125mg amoxycillin per 5ml in 60ml or 100ml bottles.
Syrup Forte: 250mg amoxycillin per 5ml in 60ml or 100ml bottles.
Paediatric drops: 125mg amoxycillin per 1.25ml in 10ml bottles with calibrated dropper.
Injection: Vials containing 250mg or 500mg amoxycillin.

Precautions
Reduced dosage is required in patients with impaired renal function.

Contra-indications
Penicillin hypersensitivity.

Side-effects
Side-effects, as with other penicillins, are usually of a mild and transitory nature; they may include diarrhoea, indigestion or an occasional rash, which may be either urticarial or erythematous: in either case it is advisable to discontinue treatment.

Bencard

A Division of Beecham Pharmaceuticals, Brentford, England.
Full information is available on request from the company.

THE PHARMACIST

JOURNAL OF THE CHAMBER OF PHARMACISTS — TRADE UNION

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Cover

Front Cover was created on a Macintosh with Mac Print by Charles Cassar and printed with the Apple Laser Writer. Ink drawing of Matricaria chamomille, a local medicinal plant by Charles Cassar. The article Matricaria chamomille by A. Gatt is on page 17.

The opinions expressed in THE PHARMACIST are not necessarily those endorsed by the Chamber.

EDITORIAL

Memorandum

The Memorandum of the Chamber of Pharmacists — Trade Union has been finalised and is being discussed with the political parties. It is a documet which represents the policy of the Chamber a policy which has developed over the years. It is not only intended for the political parties but should be read and studied by all those who in some way or another are in a position to take decisions which effect pharmacy e.g. Health administrators, etc.

LEGISLATION — AN EYEWASH?

A recurrent theme in the memorandum is the lack of enforcement of legislation. This also came up in the forum entitled, 'Is legislation helping us to fight drug abuse?' Any legislation without the necessary enforcement, without the ability of finding and doing justice with the violator is not worth the paper it is written on but only serves as an eyewash; as a pretence that things are improving or under control.

Not only has the lack of enforcement of legislation become chronic but things have moved a step further. At a time when one would expect a caretaker government to do little more than being a caretaker administrator, not so the Minister of Health. Two amendments were made to regulations governing the licencing of pharmacies.

The first amendment adds half the tourist beds in a particular locality to the resident population for the purpose of calculating the population ratio per pharmacy.

The second amendment removes the pharmacist licensee, a concept which was introduced in the legislation of 1984.

These have both been made to suit particular cases. It seems that it is the intention of the powers that be to destroy the progress made through the regulations of 1984.

In our opinion there is an inherent lack of understanding as to what the pharmacy profession really is. This lack of understanding of pharmacy can also be seen in a recent move which replaced the Chief pharmacist by a medical doctor as administrator of the government Medical stores. We are sure that no one can run these pharmaceutical services better than a pharmacist.

The regular drain of pharmacists from the hospital is a problem which must be tackled and the true reasons identified. We must ask — What is the work assigned to these pharmacists? Are there any particular problem areas which encourage pharmacists to leave? What is the remuneration of these pharmacists? Do they have professional recognition? Should not the whole structure be reorganised?

We have put forward a number of questions, questions which a new administration will have to answer. We are sure that the Chamber will be more than willing to help in a study of the matter.

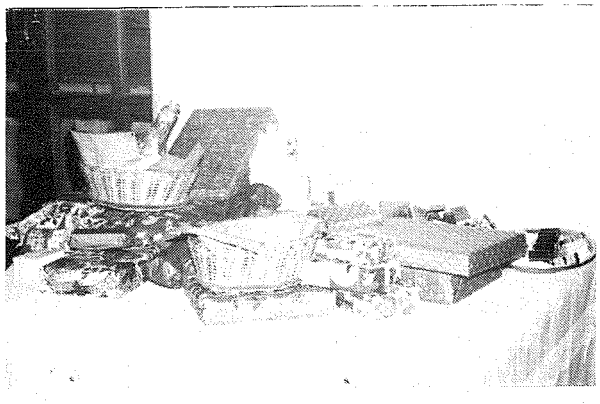
Christmas Dinner 1986

USHERING IN THE CHRISTMAS SPIRIT . . .

The annual Christmas event, organised by the Chamber of Pharmacists was held on the 12th December 1986 at the 'La Dolce Vita' Restaurant, St. Julians.

The charming atmosphere of this restaurant was regaled with festive decorations, mistletoe, streamers, ballons, etc. Candlelight added to the suggestive atmosphere. Pharmacists and their guests were in for a pleasant surprise as each one found a gaily wrapped gift on his/her plate, a Rapt aftershave for the gentlemen and a Puhl gift set for the ladies, very generously donated by Mr & Mrs Farrugia of Beautimports Ltd. Colourful paper hats and crackers completed the festive picture.

Mr and Mrs Farrugia of Beautimports Ltd.



As promised, good food was served throughout and went down well to the soft tune of Yuletide songs.

Your attention please! Ladies and gentlemen . . .

President Mrs Maria Brincat then rose to deliver her customary short address, after which raffles took the limelight with many beautiful presents being won by all. A particular raffle in aid of the Caritas Rehabilitation Centre raised Lm52; these will be presented to a Caritas representative at the next 'Pharmacists Against Drug Abuse' activity to be announced soon.

The raffled gifts were the generous donations of the local agents listed below:

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UNION NEWS

EXTENSION STUDIES 1987

NUTRITION

The Chamber of Pharmacists has organised a series of lectures and a forum on NUTRITION in this year's Extension Studies Programme, a subject which is often taken for granted.

4th March INFANT NUTRITION
Mrs. M. Gatt, B.Pharm.

11th March DIETARY TRENDS IN MALTA. IS THERE CAUSE FOR CONCERN?
Ms. M. Bellizzi, B.Pharm., M.Sc. (Lond.)

18th March Forum:
PREVENTION OF NON-COMMUNICABLE DISEASES. WHAT CAN THE PHARMACIST DO?
Speakers: *Ms. M. Bellizzi, B.Pharm., M.Sc. (Lond.),* Head of Nutrition Unit.
Dr. J. Cacciottolo, M.D., M.R.C.P., M.R.C.P. Consultant Physician
Dr. G. Galea, M.D., M.Sc. (Lond.), Head of Health Education Unit.
Chairperson: *Mrs. M. Brincat, B.Pharm.*

This year's Extension Studies were sponsored by:—

IMPEX Ltd., Impex Court N/S off Main Street, Mosta.

VIVIAN COM. Co. Ltd., Sanitas Building, Tower Street, Msida.

GEORGE BORG Ltd., 26, Merchant Street, Valletta.

ANNUAL GENERAL MEETING

The annual general meeting will be held on 25th May at 7.30 p.m. at the Federation of Professional Bodies, Paceville.

LETTER TO THE EDITOR

Bioavailability of Frusemide Tablets

Dear **Madam,**

The article on the Bioavailability of Frusemide Tablets by Dr. Anthony Serracino Inglott (**The Pharmacist,** January 1987) is an in-depth piece of research of geat practical value. We need more of such investigations — particularly with emphasise on **in vivo** tests — at a time when the commercial production of medicinal preparations is growing so rapidly and when, in consequence, the choice of the most effective drug becomes difficult.

It is heartening to see your contributor leading the way in this quest and providing a useful model for Maltese pharmacists on how to carry out research on the therapeutic effectiveness of medicaments in common use.

The results of such investigations deserve the appreciation of the practising physician and surgeon who when prescribing a drug will feel confident that its administration will be followed by the desired and expecte dtherapeutic benefits. The publication of such original articles will also serve to strengthen the academic and ethical relationships linking the medical and the pharmaceutical professions and to dispel the impression that pharmacy and medicine are independent exercises when basically they are but two inseparable facets of the same art and science of healing.

Yours faithfully,

Dr. Paul Cassar

Balzan

LOCUM SERVICE

The Chamber of Pharmacists will be organising a Locum service.

ALL PHARMACISTS who wish to participate in the scheme are asked to write to the secretary giving details of the dates and times when they are available for locums.

F.I.P. NEWS

46th INTERNATIONAL CONGRESS OF PHARMACEUTICAL SCIENCES OF F.I.P.

Helsinki . . . Chernobyl Notwithstanding!

Mary Ann Felice Sant Fournier, B.Pharm., M.Phil.

The Congress announcement appearing in 1986 issues of F.I.P.'s official journal, 'Pharmacy International' assured participants that "as far as the Chernobyl catastrophy and its consequences are concerned, there is no dangerous radio-activity in Finland" (June '86) and "foreign customers may be informed, without reservation, that the situation in Finland is completely normal; all food on sale being completely safe." (July '86). But, as we all know, the Maltese are, by nature, diffident and perhaps this time we may concede the benefit of the doubt and not 'harass' colleagues for not rushing to finally "meet Harry" at the Helsinki appointment!

Fortunately however, over 1700 pharmacists attended this year's congress and amongst them was our 'roving reporter', Harrison K. Abuthiate; here he is, punctual as ever, with his Helsinki Congress report:

LETTER FROM KENYA

FIP-86 HELSINKI

The 46th F.I.P. International Congress of Pharmaceutical Sciences was organised in Helsinki, Finland from 1—5 September 1986.

Over 1700 Pharmacists registered to attend this year's congress which was held in the magnificent Filandia Hall. This year there was no general theme associated with the congress. The Board of Pharmaceutical Sciences of F.I.P. presented a programme whose emphasis was on several symposia with either a post graduate education character or with topics which represent timely and interesting new developments of the profession of pharmacy and pharmaceutical sciences or which represent relevant discussion items for pharmacy in general e.g. side effects of drugs and sexuality by Prof. Erik Khrige, Division of Pharmacology, Department of Pharmacy, University in Helsinki, Finland; ulcers and different types of treatment by Dr. Lars Olbe, Department of Surgery, Samgren Hospital, Gotenborg Sweden; vomiting and diarrhoea and constipation by Prof. H.K. Roth; mechanisms of membrane transfer of drugs by Prof. William I. Higuchi, The University of Utah Salt Lake City, Utah 84112; Rate controlled drug delivery systems by Prof. L.F. Prescott, Dept. of Clinical Pharmacology, The Royal Infirmary, Edinburg Scotland; Impact of Patients' non compliance on drug costs by Dr. Enlund, Dept. of Social Pharmacy, University of Kuopio Finland, and 'The Traditional Chinese Medicine Today' by Prof. Ding Guang-Sheng, Shanghai Institute of Materia Medica, Chinese Academy of Sciences, Shanghai, China. The inaugural lecture was delivered by Dr. Pekka T. Mannisto on the topic "Erythromycins — Problems but also progress". The highest award for Pharmacy by F.I.P., the Host-Madsen medal was awarded to Prof. T. Nagai, Dept. of Pharmaceutics Hoshi University Ebara, Shinagawa-Ku, Tokyo, Japan. He gave a lecture on Topical Mucosal Adhesive Dosage Forms. In the studies with his colleagues, they produced several topical mucosal adhesive dosage forms containing hydroxypropyl cellulose for carcinoma colli, then oral mucosal dosage forms for absorption of insulin and adhesive tablets for aphtous stomatitis, and a powder dosage form for nasal absorption of insulin.

The congress changed venue from Filandia Hall to the Exhibition and Congress Centre at a suburb of Helsinki as the Filandia Hall was reserved for Helsinki Festival.

Bahra Singh — Secretary of the Pharmaceutical Society of Kenya and I manned the stand announcing the 4th Commonwealth Pharmaceutical Association Conference Scheduled for Nairobi, Kenya 9—13 Mach 1987.

(continued on page 15)

Declaration

by the International Pharmaceutical Federation (F.I.P.) Helsinki, 1986

THE ROLE OF PHARMACISTS IN THE EVENT OF A NUCLEAR CONFLICT OR CATASTROPHE

The International Pharmaceutical Federation (F.I.P.) embodies pharmaceutical associations from 51 countries.

More than 700,000 pharmacists are actively engaged in health care worldwide in various specialisations including: university (research and teaching), hospital, industry, community practice, military, clinical analysis, press and scientific documentation, official drug control laboratories, drug distribution, medicinal plants, etc.

Each year F.I.P. organises an international congress with a participation of between 1,500 and 2,000 pharmacists for a discussion of the latest scientific and professional developments including the registration and quality control of pharmaceutical products on a worldwide level.

The 1986 Congress was held in Helsinki during the first week of September, when the following declaration was adopted by the members of the Council and the Assembly of Pharmacists:

Having noted the conclusions reached by W.H.O. which stated:

'As doctors and scientists, the members of the Committee feel that they have both the right and the duty to draw attention in the strongest possible terms of the catastrophic results that would follow from any use of nuclear weapons.

The immediate and the delayed loss of human and animal life would be enormous, and the effect on the fabric of civilization would be either to impede its recovery or make recovery impossible. The plight of survivors would be physically and psychologically appalling. The partial or complete disruption of the health services would deprive survivors of effective help. The Committee is convinced that there is a sound professional basis for its conclusions that nuclear weapons constitute the greatest immediate threat to the health and welfare of mankind. It is not for the Committee to outline the political steps by which the threat can be removed; but mankind cannot be secure until that is done.'

Having given consideration to the role that pharmacists would be called upon to play in the aftermath of an international or accidental discharge of radiation from nuclear weapons or from a catastrophe arising from an accident in the use of nuclear energy for industrial purposes:

The International Pharmaceutical Federation (F.I.P.), a responsible organisation concerned with the health and welfare of all members of the human race, calls upon governments and governmental authorities worldwide to:

(1) Actively pursue and promote policies aimed at the elemination of the threat of nuclear war.

(2) Ensure that the most advanced methods of containment of radiation are employed in every industrial application of nuclear power.

(3) Ensure that an appropriate and adequate supply of drugs required for the treatment of radiation illnesses are maintained at all times.

(4) Provide a readily accessible supply of protective clothing for all persons likely to be called upon to continue to provide community services in areas where radiation levels could endanger their health.

In accordance with previous 'Declarations', F.I.P. wishes to remind governmental and non-governmental, national and international organisations, that it would be in their own and the public's interest to consult and involve pharmacists and their professional bodies, whenever they are called upon to resolve matters concerned with drugs and pharmaceutical products.

Helsinki, September, 1986.

PADA

How far is legislation helping us to fight drug abuse

Mary Anne Ciappara B.Pharm.

Pharmacists, doctors and members of the Caritas Rehabilitation Centre participated in a Forum entitled 'How Far is Legislation Helping Us to Fight Drug Abuse'. This forum was chaired by pharmacist, Mary Ann Sant Fournier, who is also a member of the Caritas Core Group for Drug Prevention and Action.

The subject was ably tackled by Magistrate Dr David Scicluna, the magistrate who hears all the drug cases on the island except those that involve trafficking of drugs on a large scale, and Dr Joseph Zammit McKeon, a lawyer who is experienced in this field and who has delivered a number of interesting talks on this subject. This was another activity in the 'Pharmacists Against Drug Abuse' campaign being run by the Chamber of Pharmacists.

TO COMBAT THE PROBLEM OF DRUG ABUSE

Magistrate Scicluna opened his speech by saying that "Legislation on its own is insufficient to fight drug abuse and one must not overestimate, its importance." In order that any programme to prevent drug abuse be effective, there has to be simultaneous action in at least five different areas:

1. Utopically eliminating, but in practice reducing the supply of drugs from abroad.
2. Increasing the effectiveness of the police force. These two are interrelated and call for a well-trained and efficient police force and custom personnel, who must be properly equipped and staffed and with a free hand.
3. More effective programmes to treat and rehabilitate addicts like Caritas Rehabilitation Centre.
4. Mounting health education programmes on the dangers of drug abuse for youngsters, parents and teachers.
5. Tightening control on the distribution of prescription drugs.

Specific Legislation

A strategy comprising all these separate actions would be incomplete without specific legislation — intended to have a deterent effect. The principal laws are the Medical and Kindred Professional Ordinance and the Dangerous Drug Ordinance. Recent amendments to these two laws regarding the punishments that are prescribed by the law are very high and a great deal of discretion lies in the hands of the court; penalties inflicted in the Magistrates' Court being substantially lower than those in the Criminal Court.

Do Legislative Measures serve as a Deterence?

Quoting what was said in Parliament to describe the pusher: "annimal feroċi li għandu jiġi maqful għal termini twal u jiġi ikkastigat bl-aktar mod sever, biex b'dan nagħmlu lezzjoni minnu", harsh penalties are enacted in order to act as a deterent.

The punished offender is likely to be put off from committing the same offence again, once a severe penalty is imposed on him. Under our Law, a person committing a subsequent offence is deemed to be a residivist and the court besides applying the harsh penalties which are prescribed under that particular law is also authorised to increase the punishment. But one has to be cautious for if a very severe penalty is imposed for a smaller crime, then that individual can become dangerous to society because he will bear a grudge towards it. For a number of people in any society, the deterent effect lies in the probability of detection and conviction rather than the kind or amount of punishment. Malta being a small community, one can talk more of deterence than in a larger country.

The deterent element is not effective against the professional criminal, where the risk of prison is part of life, and whose concern is not to get caught. One reason why a person returns to pushing drugs is that it is a very lucrative activity. All pushers know that addicts will never give evidence against them.

Impart Justice

The punishments give quite a degree of discretion to the court because there is a minimum and a maximum, and besides the court can also

Criminal Court	Imprisonment	Fine
In the case of selling and dealing in psychotropic drugs	4 years — 20 years	Lm1,000 — Lm50,000
Possession of psychotropic drugs	12 months — 10 years	Lm 200 — Lm10,000
Magistrate Court	**Imprisonment**	**Fine**
In the case of selling and dealing in psychotropic drugs	6 months — 5 years	Lm 200 — L 2,000
	—	Lm 100 — Lm 1,000
Possession of psychotropic drugs	3 months — 12 months	—
	3 months — 12 months	Lm 100 — Lm 1,000

go below the minimum. It can impose no punishment at all by placing an individual on probation or else discharge him conditionally. This in many cases can have a deterrent effect.

Magistrate Scicluna said that fortunately, what they are trying to do is examine each particular case on its own merit. Sometimes the court does not impose punishment prescribed by law but gives an individual a second chance (soft option).

"I believe that it is the duty of every Judge and Magistrate to impart justice rather than apply the law."

When a person is brought before the court, his social and family background, his age, whether a first time offender, or with a previous record of criminal offences, are looked into.

Traffickers are considered by court, as murderers, as they can kill with the drugs they're providing, and imprisonment and hefty fines are imposed.

Most of the cases reaching the courts are of addicts. An addict needs help. He is put under probation under the care of a probation officer, and ordered to attend the Rehabilitation Centre run by Caritas. In these cases it is important for the court to carry out follow up programmes on these individuals. Magistrate Scicluna mentioned the example of a youth who was brought before him a year ago, and who has now made a success of his life after attending the Rehabilitation Centre run by Caritas.

Some of the youngsters besides being charged with possession are also charged with trafficking. The court is giving a very wide interpretation of the words 'trafficking' and 'dealing', the question of profit or not is not important. If the circle of drug abusers has increased even though no profit has been made, then he is a pusher. An example is a case of when a group of youngsters pass a joint around. The difference lies in the punishment; a hefty fine being imposed as against imprisonment.

There is the anomolous situation of when a person is brought to Court and is proved to be a **registered addict.** The law authorises the court not to pass sentence but to send him to an institution as is designated by the Minister of Health for carrying out his rehabilitation, i.e. the court can only send them to Mount Carmel Hospital.

Food for Thought

These are some recommendations which Magistrate Scicluna would like to see implemented. In U.K. there is an interdepartmental group of Ministers which is adviced by a council. The idea is to ensure co-ordination between the various departments in order to set up a proper plan of action. This group in turn is advised by a council composed of experts in the various fields: education, medical, etc. "It is something which we do not have, something which I would like to see in the future."

THE LATEST AMENDMENTS BORDER ON THE UNCONSTITUTIONAL

Dr Zammit McKeon commented whether the law today reflects what Magistrate Scicluna is trying to do. The Magistrate's approach to the problem of Drug Abuse is humane; in that he understands the case, goes to the root of the problem and goes out of his way to meet the offender. The latest amendments are everything but humane. They are an emergency law. Is the

Problem of Drug Abuse in Malta an emergency situation so that we should depart from certain constitutional safeguards which a person has?

Powers of Attorney General

Our Constitution is a hybrid between the accusatorial and the inquisitional. Through the amendments, the powers given to the attorney general could border on the unconstitutional. The attorney general has powers to impose on the court itself the mode of punishment. It is upon the discretion of the attorney general to decide to which court, whether a magistrate or criminal court (trial by jury) the accused is brought to. The powers of the attorney general are widespread. This is also the case in the method of appeal. Normally he can appeal in 7 or 8 cases which are basically points of the law. Under this law he can also appeal on a point of fact.

Element of Conspiracy

In these amendments, the element of conspiracy (organised crime) has been introduced. Nevertheless the law does not distinguish a 17 year old pusher from the person who organises the whole traffic. While Magistrate Scicluna tackles the case from a humane aspect, another judge/magistrate could look at it from a different aspect. The penalties that are prescribed by the law are too harsh.

Principle of Extra Territoriality

These amendments to the Dangerous Drugs Ordinance created the principle of extraterritoriality. A person, who is a citizen of Malta or a permanent resident dealing in trafficking of drugs or conspiring (promotes, organises, finances) with others outside these islands, is liable to conviction and punishment under this law. Various problems can arise as a lot may depend on what is happening abroad, e.g. on foreign experts, and control by authorities.

Law is Creating a Deterence, But no Redemption

In cases of both trafficking and promotion of conspiracy, the court at the request of the prosecution, orders forfeiture of any immovable property. If the trafficker is not the owner, then it imposes a fine. It forfeits all the money which would have been earned from these dark dealings even if they are in the hands of a third party. Notwithstanding that we have a system where the accused is presumed to be innocent, until he is proven guilty, the court at the request of the prosecution, freezes the transfer of immovable property. There is a provision to allow a maximum of Lm6,000 for his needs and his family to live on.

These forfeitures whether money or property go to the Maltese Government. The law is erecting a deterence, but is not erecting an element of redemption. One would expect it to be used in the Rehabilitation Centre run by Caritas, or one run by the Government or else by the police to help them tackle the problem.

Detention During Enquiry .

While the enquiry is going on the court does not give a person the right to bail. This is normally the case only in crimes leading to life imprisonment or against safety of government. Even the court has a limited time of 20 days to handle the case

There is diminution of punishment by 1 or 2 degrees if a person helps the court. The courts still have the right to go under the minimum. Another exception in these laws is that the evidence of an accomplice is enough to grant conviction (normally evidence of accomplice is not admisable unless corraborated by other witnesses).

Elimination of Drug Abuse

Dr Zammit McKeon commented that the deterent element could be effective on certain people but not on organised crime. These provisions by themselves do not eliminate the possibility of organised crime in this country. When we start legislating for the exception, abuse can be created. Principles of equality, freedom of movement, right of a fair trial are being questioned. The Attorney General has a lot of power and it is difficult for a defence lawyer to handle a drug case under these situations. A drug problem cannot be eliminated or reduced by having legislation for our emergency situation or one that gives emergency powers to one party to the prejudice of the other.

DISCUSSION

Which are the drugs most abused of locally?

New prescription forms of narcotic and psychotropic drugs were introduced in 1984, to curtail the abuse of prescription drugs. Computerisation of these prescriptions was envisaged so that problem areas could be detected. However, to our knowledge no processing by computer is being done. From the 1st February 1987, those patients who are in need of psychotropic and narcotic drugs will require a Control Card issued

by the superintendent of Public Health in order to obtain their prescribed requirement. Is the Department introducing something which it is not prepared to handle or able to handle but fails to do it? These control cards are going to involve pharmacists and doctors with increased paperwork. Patients are going to be subjected to a lot of useless anxiety, and are given an emergency supply of three days, until the card is issued. It also discourages doctors from prescribing the medicine they consider best for their patient. The needs of the genuinely sick under doctor's care are being sacrificed

The Real Problem

A number of participants believe that our local problem is heroin addiction, and not psychotropic drugs. Drug addicts obtain heroin illegally as it cannot be prescribed. Heroin is a far superior drug to morphine, in myocardial infarction and terminal cancer, yet it is **not** available for use for medicinal purposes.

Though we know that there are heroin addicts, these are seldom prosecuted — due to failure of the police and custom forces. Most of the cases brought before the courts are Cannabis addicts.

Registered drug addicts are known to the police force and they are subject to continuous surveillance. A register with the list of Heroin addicts does not exist at the Police Department and presently three cases are pending in court of registered drug addicts charged of being in possession of Heroin.

A lot of regulations are made and though they may impress, in reality they achieve very little to fight the problem of drug abuse. The Dangerous Drug Ordinance does not distinguish, between one drug and another. The penalties given for someone convicted of being in possession of Cannabis sativa is much lower than that of possession of Heroin, so the court without realising is making a distinction between hard and soft drugs.

If we have a drug problem we have to define it, as suddenly everything becomes a drug. If we put them in their proper perspective alcohol comes first followed by cigarettes. Psychotropic drugs like Benzodiazipines are of more benefit than harm to society if used correctly. They help a person to go from a nervous wreck, back to normal life style.

Education

Our major concern is to educate the public both young and old on the problems of drug abuse. As a former drug addict said in a recent forum, if he had known the facts, he would never have started on drugs. Pharmacies and doctor's clinics can become distribution points of leaflets on information on the drugs of abuse.

Conclusion

This forum was an initial effort and other activities should be organised for all pharmacists and doctors so that together they discuss a subject which is of interest to both professions.

LETTER FROM KENYA

(continued from page 8)

F.I.P. Assembly of Pharmacists met on Wednesday 3rd September. This assembly was created by the new statutes of F.I.P. in order to offer members an opportunity to participate in a broadly based discussion. The items discussed were:—

(a) Presentation of the results of the council meeting and of the activities of the Federation over the past year by Mr. L.G. Felix Faure, Administrative Director.
(b) F.I.P. involvement in continuing education by Prof. Breimer, Scientific Secretary.
(c) New International Code of Ethics for Pharmacists by Mr. A. Bedat, President F.I.P.

A declaration was adopted by the members of the council and Assembly of Pharmacists. (See page 9)

This year's F.I.P. Third World programme discussed the theme:— "Treatment and Prevention of Diarrhoea Diseases Pharmaceutical Involvement" under the Chairmanship of Prof. P.F. D'Arcy, Vice President F.I.P. speakers included Dr. M.H. Merson, Director Diarrhoea Diseases, Control Programme WHO Geneva.

The Congress ended with Sectional Dinners on Thursday 4th September 1986 and Final Dinner/Dance at the Dipoli Centre on Friday 5th September 1986.

The newly elected President of F.I.P. is Dr. J. Oddis of U.S.A. The next Conress will be held in Amsterdam, Holland 1—5 September 1987 to mark the 75th Anniversary of F.I.P.

Harrison K. Abutiate B. Pharm (Hons)
Zone Manager East & Central Africa
Merck Sharp Dohme International
Nairobi, Kenya

MEDICINAL PLANTS

Matricaria chamomilla

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History

The Matricaria chamomilla has been used as a domestic remedy since early times. The wild plant is indigenous in England and the double variety which has risen as a result of cultivation was well known in Malta during the sixteenth century.

The name **Roman** was given to the Chamomille by the German physician Joachim (also known as Camerus). This name was given because of the abundance of the Chamomille in the neighbourhood of Rome. About the same period the German botanist Bock (also called Tragus) named the plant **Chamomille** from two Greek words meaning 'apple of the ground' since the plant grows close to the ground and has an odour which was thought to resemble that of the apples.

Pharmacology

Studies on the pharmacological actions of the Matricaria chamomille are not numerous. In the last 33 years the following studies appeared:

Janku, and C. Zita (1954)[1] observed some antihistaminic and antiphlogistic action on rats.

Studies conducted by M. Holub and V. Herout (1957)[2] showed that the chamomille oil has some granulating and epithelizing action.

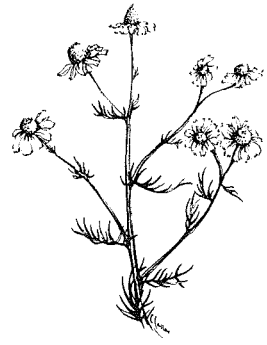
O. Isaak (1969)[3] noted some antispasmolytic actions of the chamomille on rats.

The possible antibacterial activity of the chamomille oil was investigated by Abbag, Yorself and Planti (1972).[4] The oil is introduced in plates containing cultures of Gram positive bacteria and Gram negative bacteria. Gram positive bacteria appeared to be more sensitive. These continued to study the antibacterial action of the chamomille oil against staphylococcus aureus. A reduction of growth is observed and the concentration of the oil appeared to be inhibitory to tested staphylococcus aureus. The authors suggest the incorporation of volotile oil in the topical application of staphylococcus infections.

Benner, Marshall and Howard (1973)[5] described an anaphylactic reaction to chamomille tea.

Gould, Laurence and Ramana (1973)[6] noted that when patients were given for several days chamomille tea twice a day, they experienced a slight increase in the medn. branchial artery pressure. No other haemodynamic changes were observed. These authors observed that ten out of twelve patients experienced drowsiness after drinking the beverage.

Studies on the antimicrobial action of the chamomille tea by Zeits and Arkedera (1975)[7] again showed that the oil is more effective in inhibiting the growth of gram positive bacteria. B. subtilis was observed to be the most susceptible.



Matricaria chamomille.

The main pharmacological actions of chamomille can be summerized as:

(i) slight antihistaminic action
(ii) slight antispasmolytic action
(iii) granulating and epithelizing action
(iv) antimicrobial action
(v) sedative effect.

The dose of chamomille oil is 0.03 - 0.2 ml and of the dry plants 8g - 16g. The lethal dose as described by Horakara[8] is LD^{50} in mousse 11.350 mg/kg by oral route, LD^{50} in rats 14.850 mg/kg by oral route.

Local Use of Chamomille

In Malta the Matricaria chamomille is still widely used. The recorded therapeutic uses of the chamomille are:

a. for the treatment of symptoms associated with the upper digestive tract, such as to relieve the experience of fullness after a heavy meal.
b. in the form of a gargle to produce a soothing effect on the inflamed gingival and even in pharngitis.
c. in the washing of the skin.
d. to treat acute and chronic rhinitis.
e. in shampoo formulations.
f. to treat cracked nipple and nipple rash.
g. as an aromatic bitter to stimulate appetite.
h. as a flavouring agent.
i. in large doses as an emetic.
j. applied to the skin to treat minor inflammatory conditions.

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AUGMENTIN

(clavulanate-potentiated amoxycillin)

NEW SYRUP PRESENTATION

PRESCRIBING INFORMATION

Indications:
Chest, ear, nose, throat, genito-urinary, skin and soft tissue infections including those caused by ß-lactamase producing organisms.

Dosage:
Adults and children over 12 years one AUGMENTIN tablet (375mg) three times daily.
Children 7-12 years 10ml AUGMENTIN syrup (312mg) three times daily.
Children 2-7 years 5ml AUGMENTIN syrup (156mg) three times daily.
Children 9 months – 2 years 2.5ml AUGMENTIN syrup (78mg) three times daily.

In severe infections these dosages may be doubled. Treatment should not be extended beyond 14 days without review.

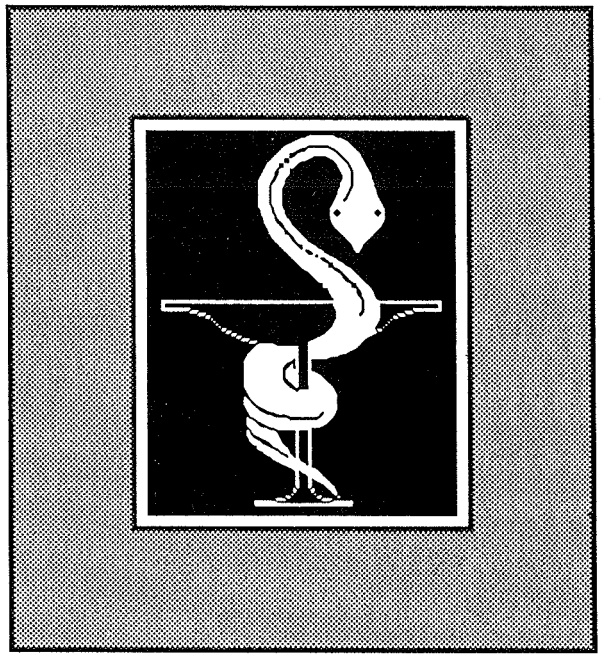
Contra-indication:
Penicillin hypersensitivity.

Precautions:
Safety in human pregnancy is yet to be established. Oral dosage need not be reduced in patients with renal impairment unless dialysis is required.

Side-effects:
Uncommon, mainly mild and transitory, eg diarrhoea, indigestion, nausea, vomiting, candidiasis, urticarial and morbilliform rashes.

If gastro-intestinal side-effects do occur they may be reduced by taking AUGMENTIN at the start of meals.

Presentations:
375mg AUGMENTIN tablets each containing 250mg amoxycillin (1) and 125mg Clavulanic acid. (2)
156.25mg AUGMENTIN syrup. Powder for preparing fruit flavoured syrup. When dispensed each 5ml contains 125mg amoxycillin (1) and 31.25mg clavulanic acid. (2)
(1) as the trihydrate, (2) as the potassium salt.
Not all presentations are available in every country.



MEMORANDUM

BY

THE CHAMBER OF PHARMACISTS
Trade Union

April 1987

This memorandum is a synthesis of the policy of the Chamber of Pharmacists - Trade Union - a policy which has developed over the years. It has been compiled to bring to the attention of all concerned the problems which face Pharmacy in Malta today. Some of these problems have been with us for many years and it is about time that these be solved without any further delay.

We strongly feel that knowledge of our problems by the politicians, who are the persons responsible directly for legislation and indirectly for the enforcement of this legislation, is the only way that a solution of these problems can be approached. Some of these problems discussed below do not only concern the pharmacy profession and its members per se, but effect the general public, exposing the population to unnecessary risks.

THE PHARMACIST — Definition

It is easy to define the pharmacist as the graduate from a B.Pharm. University course. But this merely describes his academic classification. Indeed, one may ask:

1. Who is the pharmacist?
2. What are his areas of work?
3. What is his role in society?
4. What are his responsibilities?

The pharmacist is the product of four years University education in Pharmacy. The traditional aspects of pharmacy are still there, i.e. preparation of medicines — pharmaceutics. However, there is much, much more to modern pharmacy. These days with the discovery and marketing of so many new and potent drugs, it has become imperative for the pharmacist to have intensive tuition in pharmaceutical chemistry and pharmacology. Furthermore, the increasing clinical involvement of pharmacy has resulted in the emergence of clinic pharmacology, a topic which forms an integral part of the pharmacy students' education.

The image of the pharmacist is most often linked with his role as managing pharmacist in a pharmacy. He is the member of the health care team, with an intensive academic training in drug treatment and therapy. He is responsible for the dispensing of medicines, for patient information and patient education on his therapy. He must see that the correct dosage has been prescribed, and keeps a lookout for drug interactions. Other areas of work are in hospital, industry and as medical representatives.

In hospital, his work may be directly linked to patient care. He may also be involved with administration, procurement and distribution of medicines.

As medical representatives, pharmacists are in a unique position to provide the members of the medical profession with accurate and truthful information on new medication and dosage forms available.

The following is the Budapest Declaration of FIP. This declaration may be regarded as a charter for pharmacy. It is also a charter of safeguards for the patient who is morally entitled to receive his medication via an expert professional — the pharmacist.

We urge all politicians to study this document carefully and take immediate consideration of the suggestions put forward. Only through the implementation of the suggestions included in this memorandum can Pharmacy in Malta make the necessary advance to reach current international pharmacy practice.

THE BUDAPEST DECLARATION OF THE INTERNATIONAL PHARMACEUTICAL FEDERATION

— Having noted, like WHO, that medicaments are becoming increasingly important, within the health policies of countries world-wide;
— Having noted that many persons who have only superficial knowledge of drugs and pharmaceutical products are engaged in the distribution of pharmaceutical products for profit purposes only;
— Having noted that practically everywhere there is an increasing number of declarations, opinions, erroneous statements, about drugs and pharmaceutical products by persons who although well intentioned are generally poorly informed;

The International Pharmaceutical Federation (FIP) reaffirms and emphasizes that:

1. Drugs and pharmaceutical products should not be regarded as normal items of commerce; they are very complex aids to health care.
2. Only specialists possess an in-depth knowledge of drugs and pharmaceutical products, i.e. their composition, preparation, handling, dispensing, action, side-effects, drug-drug and drug-food interactions, etc. Only such specialists are qualified to give appropriate information and advice to the patient receiving pharmaceutical products on prescription or when the patient obtains them on his own initiative.
3. Pharmacists are the specialists who have the necessary integrated knowledge of drugs and pharmaceutical products. They have completed university studies involving subjects related to this knowledge. Moreover, this knowledge is strengthened through professional practice and the updating of this knowledge.

Consequently, FIP wishes to remind governmental and non-governmental, national and international organizations that it would be in their own and the public's interest to consult and involve pharmacists and their professional bodies, whenever they are called upon to resolve matters concerned with drugs and pharmaceutical products.

1. THE MANAGEMENT OF COMMUNITY PHARMACIES

A pharmacy is not a shop. It is the place where a professional, the pharmacist, practises his profession. He is there not to retail medication but to dispense medicaments whether over the counter or by prescription. He is the public's guardian to the correct use of medication.

There are about 140 pharmacies on the island. Unfortunately of these not even 100 are professionally run. The legislation to regulate pharmacies exists. The legislation defining the running of pharmacies by pharmacists exists, however the will to enforce this legislation has been absent for years. Mismanagement which puts the patient at risk, is allowed to go on uncontrolled. It is of the utmost importance that Pharmacy Inspections are instituted immediately. The **inspectorate** should consist of mature people, with a special appointment and suitable remuneration to carry out such work.

The professional management of pharmacies can only be carried out by pharmacists for the safety and benefit of the general public. No one should be allowed to usurp the pharmacists' role.

2. SATURDAY AFTERNOON BY ROSTER

Pharmacy opening hours extend to over forty hours a week. In addition to this pharmacies are required to open by roster on Sunday morning every few weeks. As can be seen the working hours of a managing pharmacist, are creating hardship for our members.

If a pharmacy is to be professionally managed all the time, if the patient is to get a professional service all the time, then the pharmacist must be continuously present at the pharmacy. We are of the firm opinion that the opening of pharmacies by roster on Saturday afternoon will make it easier for this to be achieved. The same roster which applies to Sunday morning being applicable to Saturday afternoon.

The Chamber has studied the current roster and after taking into consideration the pharmacies which opened over the last few years, has drawn up a new roster which we are positive is much more convenient to the general public.

A copy of the proposed roster is presented in the appendix.

We look forward to the implementation of this proposal forthwith.

3. DISPENSING IN CONTAINERS

In Malta there exists the practice of dispensing medicines in paper bags, both in hospital and retail pharmacy. This practice is lamentable and must be discouraged outright. These paper bags are in no way suitable containers for medicines. They offer no protection from light, or moisture the latter affecting the shelf life of almost, if not all, medicines. Medicines should be dispensed in waterproof, airtight containers.

Three of the most sensitive preparations are glyceryl trinitrate tablets, choline theophyllinate tablets and potassium chloride tablets. All of these three preparations are frequently obtained from the hospital. While choline theophyllinate and potassium chloride tablets are **sometimes** issued in proper containers, glyceryl trinitrate tablets are invariably issued in paper bags. It is widely known that the potency of these tablets is lost within a few days if so dispensed. There are no visible changes, so that the patient only discovers the loss in potency when it is too late.

After repeated initiatives by this Chamber, there has been a recent move in retail pharmacy towards the use of proper containers. We would like to see this move being encouraged at the official level not only in retail pharmacy but also in the government dispensary.

4. DISPENSING FEE

As mentioned already the pharmacist has a great responsibility. He is, in a number of cases, the one to identify potentially serious complaints, suggest to patients to seek medical investigation and when dispensing prescribed medication to the patient ensures that he knows how to take it. This makes him, very often, the first and last member of the health care team to come in contact with the patient. Yet all his professional responsibility and service, is not recognised financially by the official approval of a dispensing fee.

The introduction of a dispensing fee in Malta is long overdue. For all his responsibility and care of the patient he is remunerated even less than if he had to sell a cosmetic preparation.

5. TARIFFS FOR DISPENSING OF EXTEMPORANEOUS PREPARATIONS

On January 19th at an extraordinary general meeting the Chamber of Pharmacists - Trade Union approved a list of tariffs with the aim of

standardising the fee charged for extemporaneous preparations. The implementation has been postponed pending discussions with the Department of Health which discussions have already commenced.

The extraordinary general meeting also approved a fee to be charged when psychotropic and narcotic drugs on the control card system are dispensed. The implementation of this fee has also been postponed pending discussions with the Department of Health. The aim of this fee is to compensate the pharmacist for his responsibility and for the large amount of paper work involved every time such a preparation is dispensed.

6a. LEGISLATION — REGULATION OF PHARMACY LICENCES

Much needed legislation re the opening of pharmacies came out in 1984. However volumes of legislation are worth nothing unless they are enforced. Together with enforcement, it is necessary not to treat legislation as an elastic object, to be amended and stretched to meet anyone's special needs. This happened recently when the regulation re the population ratio per pharmacy was amended to the effect that in tourist areas half the hotel beds in the area are added to the number of residents.

As if to add insult to injury, another amendment to the regulations was recently approved by the Minister of Health. This amendment removes regulation 5(5) of L.N. 31 of 1984 which said "No licence shall be granted or transferred unless licensee or transferee of the dispensary is a person who is qualified to practice as apothecary under the provisions of the Ordinance, or in the case the transferee is the husband or wife or a descendent in the direct line of a deceased licensee."

The Chamber considers this regulation as being fundamental to these licensing regulations. We regret that regulations which were issued after much consultations by the Department of Health and upon recommendations by the Chamber, were so capriciously removed without any consultation at all.

We must insist that the deleted regulation be reinserted forthwith. Furthermore, the following points should be considered for inclusion in pharmacies licensing regulations.

i. the ownership of pharmacies by pharmacists;
ii. the definition and regulation of pharmacies owned by companies. It is to be remembered that these are not mentioned at all in the existing legislation;
iii. in such company owned pharmacies, pharmacists should own at least 51% of shares;
iv. in current legislation, two licenees are required for the opening of a pharmacy — a police licence and a licence by the health department. These licences should be issued to the same person, a pharmacist.

The Chamber cannot fail to emphasize that had the prexisting law been enforced there would have been little need for much further legislation.

6b. LEGISLATION — CONTROL CARDS

In view of the current problems on drug addiction, the introduction of the control card system is understandable. It is a time consuming method, which is proving to be costly in the time involved in its implementation by the pharmacist.

The system requires monitoring by the Health Authorities and there are a number of points which must be looked into:

i. Cases have been met of two control cards being issued to the same person.
ii. Mistakes in the ID card number or address of the patient have been found.
iii. The Control cards have no serial number. They do have the I.D. card number which can be used instead of a serial number. However this is not so to date, otherwise it would certainly not be possible for one person to have two control cards.
iv. The cards bear no water mark.
v. The three days 'urgent' period is too short. A more reasonable extension is a seven day period.
vi. In some cases doctors are applying for the control cards. When these reach the patient, the patient is turning up at the pharmacy without it being signed by the prescribing doctor.
vii. It is strongly suggested that doctors prescribing narcotic and psychotropic drugs do not prescribe for more than one month.
viii. It is strongly suggested that when the Control Card is full or expires, it is to be returned to the Medical and Health Department before a new one is issued. At least at this stage, the authenticity of all signatures should be checked.
ix. Since it was felt necessary to introduce the

Control Card system, it is imperative, that when the authorities learn that a patient is misusing drugs, managing pharmacists are to be informed accordingly. It is hoped that the relevant authorities have the necessary organisation to spot such cases.

x. Had the Green Prescription forms been suitably computerised, then the control card system would never have been necessary.

xi. A register of all doctors' and pharmacists' signatures should be sent to all managing pharmacists in the immediate future.

7. DRUG IMPORTATION

The Chamber would like to emphasise that drugs are not ordinary items of commerce. The health of the patient is the primary aim. Professionals in the medical field particularly pharmacists know that a number of medicines can be obtained from different sources. Great care must be taken in choosing the right source. This is of particular importance with Government's purchasing of drugs by tender. Cheap substitutes instead of original products are generally purchased.

The Chamber would like to draw attention to the danger the patient is exposed to when price is the sole criterion employed. The Chamber carried out a study and collected information re various preparations used in the government hospital services. These are some of the results:

Cimetidine (Italian Generics)

Tests on batches of Cimetidine showed:

i. The cimetidine content was within SK & F limits.

ii. However all the batches tested failed to comply with **disintegration** specifications for Tagamet tablets. Tagamet tablets have a disintegration time of 15 minutes. The Italian generic had considerable batch to batch variation, one of the batches disintegrating after two and a half hours.

iii. **Dissolution** specifications for Tagamet are 85% of the cimetidine content is dissolved after 15 minutes. In the case of the substitute cimetidine there was considerable batch to batch variation, the batch having a disintegration time of two and a half hours yielding only 60% of the drug content in solution after one hour.

For some time after the above reports were presented to the Health Authorities, Tagamet was purchased by the Department of Health. Later a tender to another Italian firm was granted which never reached the island because the particular firm had no free sale certificate from the Italian Ministry of Health for cimetidine.

Recently there was dissatisfaction with salbutamol syrup being issued from the hospital with the result that a recent call for tenders, requested only the original brand of Salbutamol (i.e. ventolin) syrup. This is a step in the right direction.

More examples are given in the appendix.

What is necessary is to improve the present system of quality control. To date, the requirements are the presentation of a certificate of free sale in the country of origin. False free sale certificates have been known to have been presented. Though a policy of blacklisting of such firms is said to exist, it is also known that, orders from firms, after such blacklisting, have been placed.

A further problem with the use of ineffective generics is that, a failure of therapy makes it essential for a switch in medication to another product, often a newer and more expensive product.

What are the Chamber's proposals on this subject?

1. There should be no monopoly on drug importation either by government or by anyone single entity in the private sector.
2. Improved quality control — one way of implementing this is by carrying out random checks on the **received** consignment at an independent laboratory. If too expensive to be carried out here, then the foreign company should be made to pay for these tests. Surely serious companies are prepared to pay for such tests when for them the financial benefits are tenders worth thousands of Maltese pounds.
3. Even importation of the original product is sometimes not a sufficient guarantee. Some products need to be specifically manufactured for our climate. An example is the use of Flurazepan Monohydrate for countries in tropical zones. At one time, Dalmane purchased from a Britsh wholesaler was bought by the hospital. Such batches meant for the British climate are of insufficient stability for Malta.
4. There should be no delay in the granting of licences, so long as the requirements for quality control, and therapeutic activity are met.

8. DRUG ADDICTION PHARMACISTS AGAINST DRUG ABUSE (PADA)

A year ago a sub-committee **Pharmacists Against Drug Abuse (PADA)** was set up, with the aim of organising pharmacists in the fight against drug abuse through the organisation of various activities such as seminars and fora on the subject. Last year a very well attended course on Drug Addiction was held, as well as a forum entitled "Is legislation helping up to fight drug abuse?"

This group of pharmacists work in close collaboration with CARITAS. It is the intention that PADA will not remain only involved with pharmacists but will extend its activities to the whole society by equipping pharmacists with essential continuing education on this important subject.

The Chamber of Pharmacists encourages Government to keep pressing on with its fight against drug abuse:

i. by increasing police efficiency in catching pushers. Heavy penalties in themselves are no safeguard against drug abuse. The best deterrent is a surety of police efficiency in catching the culprits. (Magistrate Scicluna - Forum - Is Legislation helping us to fight Drug Abuse).
ii. through continuous education of both parents and children about the problem.

Moreover the Chamber encourages Government to recognise the contribution pharmacists can make in this field, by including pharmacists in boards which are in any way involved with drugs and medication because the pharmacist is society's expert on drug therapy.

The Chamber reiterates that the pharmacist has a unique role to play in the fight against drug abuse. He is in a key position to educate the general public and reinforce the correct use of medicines. It is a serious irresponsibility of any administration which allows unqualified people to play his role, people who, due to their lack of suitable qualification, cannot in any way give the proper guidance and advice which the pharmacist can give.

9. PHARMACY BOARD

The Pharmacy Board is the regulatory board of the pharmacy profession. "Is" is perhaps the wrong verb. It is perhaps better to state should be the regulatory board of the pharmacy profession, because repeated amendments have reduced this board of incompetence.

The Pharmacy Board was set up with the aim of regulating the practice of the pharmacy profession and ensuring the observance of the ethics which were issued by the same board shortly after it was set up.

The previous composition of the board was: Chairman, C.G.M.O., S.M.O., two pharmacists representing Government, three elected pharmacists, one pharmacist representing University, and two elected pharmacy technicians. Recent admendment to the composition of the board have resulted in a board of sixteen, while the quorum is still of six people. There are now so many non pharmacists on the board that even without a single pharmacist present, there can be a quorum.

We strongly urge that this board should be brought to its former proper balanced functioning composition immediately.

10. COUNCIL OF HEALTH — PHARMACIST REPRESENTATION

The Council of Health is the body which advises the Minister of Health on prospective legislation and regulations which fall under the Medical and Kindred Professions Ordinance.

The pharmacist is a member of the health care team, and the practice of his profession falls under the jurisdiction of this ordinance. Like doctors, and dental surgeons, he should be represented on this Council.

It is ridiculous that proposed legislation re pharmacy is put to this Council for comments and suggestions, when no member of this Council is competent in pharmacy.

11. HOSPITAL PHARMACY

The field of hospital pharmacy suffers regularly from a shortage of pharmacists. The primary reason for this repeated drain is the lack of incentives given to pharmacists in government employment.

To build a strong hospital pharmacy service one needs:

1. An adequate number of suitably qualified and adequately remunerated pharmacists.
2. A number of pharmacists should be encouraged to specialise in hospital pharmacy, if necessary by taking courses abroad.
3. It is time to recognise the hospital pharmacist as being of a professional grade both in terms of professional responsibility and financial remuneration.

12. STUDENT WORKER SCHEME

The student worker scheme in Pharmacy was introduced in 1978. Several problems came up on introduction of the new system.

Outlined breafly these are:

i. A reduction in the number of contact hours.

ii. A number of students found themselves doing work which is unrelated to their studies.

iii. The five-and-a-half month work phase is too long a period to be out of touch with study.

iv. There is a waste of the very limited University resources, because of the repetition of the academic lectures, tutorials, etc.

v. There is lack of adequate supervision during work.

The Chamber makes the following recommendations:

i. There should be an eight month study phase and a four month work phase which will increase the number of contact hours and provide adequate study time.

ii. The introduction of a pre-registration period to make up for the decreased work period.

iii. An agreement between sponsors so that students can gain experience in the various field of pharmacy, and not only in the field of their sponsor.

iv. The study and work phases should be concurrent, this will permit better utilisation of the academic staff available.

A more detailed analysis of the student worker scheme in pharmacy is presented in the Chamber's Report of June 1986.

13. HEADSHIP OF THE PHARMACY DEPARTMENT

The University is the breeding ground for new pharmacists. Only pharmacists can impart the right approach to the pharmacy profession.

The pharmacy department has been without a head for years now. Furthermore the current acting head is qualified in the medical field and has little knowledge of what pharmacy is.

The Chamber must insist that:

i. a head be appointed.

ii. the head of department should be a pharmacist with suitable qualifications in the academic field.

14. DISTRIBUTION OF FREE MEDICINES

The current system of distribution was introduced to reduce the load of people going to St. Luke's Hospital. It involves the sending of a prescription of the required medication together with the relevant pink/or yellow cards to the hospital, and later collecting the month's supply of medication from the local clinic.

When the system was introduced, there was an increase in the demand for free medicines from the hospital. The eligibility of patients for free medicines is dependent on income and on the kind o disease. Both criteria are changed from time to time.

The costs involved are:

a. The cost of the medication itself.

b. The cost of packaging each individual patient's medication (labour costs).

c. The cost of transportation and distribution at the local clinics (labour costs).

d. Professional costs are minimal because very few pharmacists are involved in the system.
— There is no patient counselling at any stage re the medication prescribed.
— There is inadequate monitoring of the requirements or otherwise of repeats. A case in point is that of a patient known to have received a supply of ampicillin for six months. Several patients do not take the medication. They either hoard the tablets or try to exchange them at retail pharmacies. A report reached the Chamber of a patient going up to his local pharmacist to exchange six boxes of Voltaren tablets.

Reduction of Costs

The distribution of free medicines to those who cannot afford them or have certain diseases is an important service. It is a service which takes up a significant portion of the health care bill and it is understandable that an attempt be made at reducing costs. This generally is done by

i. adjusting the criteria for eligibility for free medicines;

ii. using cheap generics.

Chamber's recommendations:

a. **Fee per prescription**
The general public's attitude is: if something is provided for free then take it even if only to throw it away; if the individual has to pay for it then he will buy it if he needs it and will take great care not to waste.

In view of this it should perhaps be reconsidered whether it is better to **charge a fee per prescription** in order to discourage waste as much as possible.

b. **Exclusion of certain items in favour of a better service in other areas**
With regard to certain items like acriflavine solution, plaster, glyceryl trinitrate tablets, does the end product reaching the patient cost more than the equivalent bought at a retail pharmacy? Furthermore, in the case of glyceryl trinitrate tablets, is the cost justifiable when the way these tablets reach the patient is a guarantee that these will lose their potency within a few days? It is perhaps wiser that items which cost only a few cents are excluded from the list in favour of more essential and more expensive items.

c. **Use of effective medication**
The use of cheap generics is not professionally acceptable unless measures are taken to ascertain that the generics are of the required therapeutic level. Furthermore, the use of cheap, ineffective generics results in either administration of a higher amount e.g. administration of two diuretic tablets instead of one; or a switch to a newer and a more recent medication e.g. the switch to atenolol because of the ineffectiveness of generic propranolol. This reduces or annuls any economic gains made when using cheap generics. Not to mention also, the danger to the patient, a matter discussed under drug importation.

d. **Distribution from Pharmacies**
In recent years a suggestion was put forward by the Chamber of Pharmacists that retail pharmacies should be used as a distribution points for these medicines. This will give the patient the professional pharmaceutical service required because the pharmacist present can answer any queries re therapy. This could be done against a dispensing fee.

Another method is for patients to obtain medication directly from pharmacies, the cost being then met by government. This saves on the time spent in hospital preparing the packages, and at the same time reduces the risk of mistakes being made. The patient can either pay the full cost and then receive a refund from government or pay part of the charge, the rest being paid by government to the pharmacies concerned.

15. MEDICAL REPRESENTATIVES

As already stated in the introduction, pharmacist medical representatives are in a unique position to provide the members of the medical profession with accurate and truthful information on new medication and dosage forms available.

Unfortunately unqualified people are regularly permitted to work as medical representatives. Some of these have in their possession restricted drugs, which goes against the provisions of the medical and kindred ordinance. These people with their lack of knowledge in pharmacy give the false impression that Medical representatives are mede salesmen.

The Chamber of Pharmacists also believes that doctors should not be allowed to work as medical representatives. The reasons substantiating this Chambers's objection are so glaring that we feel it is quite superfluous to list them here.

16. PHARMACY TECHNICIANS

The pharmacy technician, was previously called the assistant apothecary. The new nomenclature is a direct reflection of requirements of modern pharmacy. The shift to pharmacy practice requiring an in depth knowledge of the pharmacology of the modern and very often potent drugs has made the pharmacy technician redundant in community pharmacies.

The need for pharmacy technicians exists only in hospital, and this is where their line of work should be restricted to.

CONCLUSION

The Chamber of Pharmacists - Trade Union is committed towards the proper recognition of the status and role of the pharmacist in society to which the pharmacists' services are indispensible.

The Chamber works continuously at fulfilling this commitment by

- constantly tackling the problems facing pharmacy in Malta
- the organisation of continuing education programmes for pharmacists
- the publication of The Pharmacist
- the setting up of PADA (Pharmacists Against Drug Abuse) working in close collaboration with CARITAS (Malta).

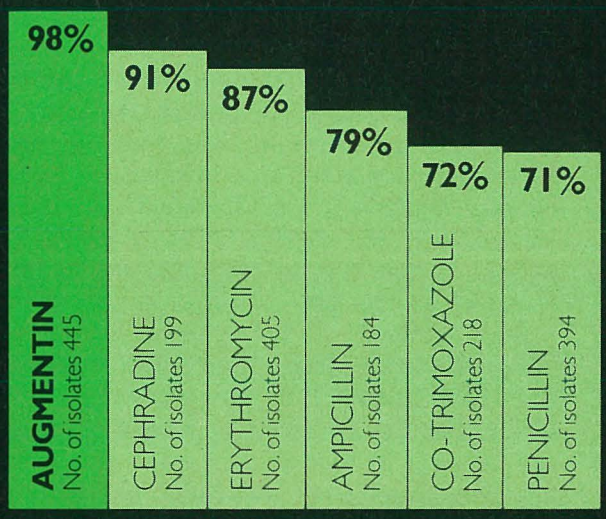
It is of course impossible for significant progress to be achieved without the necessary contribution from legislators, and all administrators responsible for the enforcement of legislation. Attention must here be drawn to the fact that the lack or insufficient enforcement of legislation is a recurrent theme in this memorandum.

This Chamber urges all politicians, and all others who are in some way involved directly or indirectly with pharmacy to study this memorandum carefully and looks forward to immediate discussions on it with all those concerned particularly with the political parties.

A CHANGE FOR THE BETTER IN CHILDREN'S INFECTIONS

Broader in Spectrum

- A broader spectrum than ampicillin, erythromycin, co-trimoxazole and oral cephalosporins
- Excellent activity against *Haemophilus influenzae*, *Strep. pneumoniae*[1,2] and *Branhamella catarrhalis*[3,4]



(General Practice isolates from Ear, Nose & Throat infections, collected during 1979-80)[5]

Outstanding in Practice

- Rapid relief from symptoms
- Excellent success rates in ear, nose and throat infections[6,7,8,9,10]
- Well tolerated, with a low incidence of side effects[6,11]

Paediatric infections (and no. of assessable patients)	Favourable Response	% Clinical Success
Otitis Media,[9] (133)	129	**97%**
Tonsillitis Pharyngitis[9] (109)	106	**97%**
Bronchitis[9] (91)	85	**93%**
Urinary Tract[9,12] Infections (50)	48	**96%**

AUGMENTIN

A performance that sets it apart

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Further information is available from:
Beecham Research Laboratories
Brentford, Middlesex, England.

An Outline History Of Pharmacy

PART II. RENAISSANCE TO TWENTIETH CENTURY*

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* *This is the second part of the extended text of a series of three lectures delivered to the Course of Pharmacy 9th to 16th May 1986.*

In the field of pharmacy, the School of Salerno produced the **Antidotarium parvum** by Nicolas of Salerno which is a collection of formulae, probably compiled in the eleventh century. It contains a reference to the ingredients that were employed to produce an early form of surgical anaesthesia. This was the **spongia somnifera** consisting of a mixture, in water, of opium, mandrake and henbane. A rag was soaked in it and applied to the nostrils of the patient to put him to sleep and render him insensitive to the pain of surgical operations.(1)

State control of the exercise of pharmacy came into being about 1240, when Frederick II, the Holy Roman Emperor and King of Sicily, introduced the licensing of sellers of drugs by the Medical School of Salerno; rules prohibiting physicians from owning a pharmacy; and regulations fixing the prices of medicaments. Fom these initial legal enactments stemmed the various laws controlling the pharmaecutical profession of our own days.

By the end of this same 13th century we come across some of the titles and denominations by which the present day pharmacist was referred to (in France) — **speciarius, apothecarius, piperarius** and **aromatarius.**(2)

Herbals. Pharmacopoeias

A basic feature in the development of the **materia medica** of pharmacy was the evolution of the **herbal** or **herbarium,** the earliest of which is that of Dioscorides already mentioned who flourished in AD 60. These herbals were the precursors of the science of medical botany. They described the plants or "simples" used in therapy, the manner and time of collecting them or "simpling" and of preserving them for the preparation of "compound" medicines.

By 1491 the **herbal** appeared in print with woodcut illustrations meant to help in the identification of plants. It became quite popular by the 16th and 17th centuries such as that of Otto Brunfels, a physician of Berne, printed at Strasburg in 1530-36.(3)

The **herbals** were the forerunners of the pharmacopoeias. Among the earliest published pharmacopoeias were those of Augsbourg in 1564, of France in 1608 and of London in 1618. By the end of the 18th century the principal cities and countries of Europe had their own pharmacopoeias — Bruxelles (1702), Sweden (1705), Madrid (1738), Switzerland (1771) and Russia (1780).(4)

The Renaissance

The Renaissance, which began about the end of the 14th century and reached its climax two hundred years later, was marked by a spirit of inquiry and the discovery and exploitation of the Americas by Spain in the 15th and 16th centuries. Hitherto unknown vegetable sources were imported into Europe from these new lands to enrich the practice of pharmacy. Three of these items were still in use until fifty years ago: (a) the bark of **Myroxylon pereirae,** from Peru, hence known as Peruvian or Jesuits' bark which yielded a balsam that was used as an expectorant; (b) the bark of **Cinchona succirubra,** containing quinine, which was employed in powder form against malaria and other fevers. It was known as Countess' Powder, afetr the Countess of Cinchon, who was said to have been cured of a fever by its administration; (c) from Brazil came the dried roots of **Cphaelis ipecacuanha** whose chief constituent is emetine and which was being used by 1672, especially in France, as a remedy for dysentery.(5)

Along with these effective drugs, however, traditional **materia medica** still included substances that had no therapeutic effect but were

Fig. 1 opposite page
The frontispiece of John Zwelfer's PHARMACOPOEIA REGIA published in Nurimberg in 1675. It is one of the earliest pharmacopoeias to be issued.


יהוה
DEUS CREAVIT MEDICUM &c DE TERRA MEDICAMENTA
PRUDENS AUTEM NON CONTEMNIT ILLA. Eccl. 38
SUB HIS ALIS
VITA BREVIS ARS LONGA
QUOD EST SUPERIUS SICUT QUOD EST INFERIUS
Honora Medicum propter necessitatem. HIS DUCIBUS Etenim illum creavit Altissimus. Eccl. 38.
PHARMACOPOEA REGIA
seu
DISPENSATORIUM NOVUM
COMPLETUM & ABSOLUTUM
cum
ANNEXA MANTISSA
PHARMACEUTICA
MDCLXXV


יהוה
DEVS CREAVIT
MEDICVM ET DE
TERRA MEDICA-
MENTA. VIR PRV
DENS AVTEM NO
CONTEMNIT
ILLA.
Eccles. cap. 38.
VITA
BREVIS
ARS
LONGA
QVOI EST
SVPERIVS
EST SICVT
INFERIVS
ANIMADVERSIONES
IN
PHARMACOPOEIAM AUGU-
STANAM EJUSQUE MANTISSAM
TERTIUM REVISÆ.
CUM
APPENDICE ANNEXA.
QUIBUS ACCESSIT
PHARMACOPOEIA REGIA
NOVA LOCUPLETATA & ABSOLUTA.
ADJECTA
MANTISSA SPAGYRICA.
CURA
JOANNIS ZWELFERI PALAT.
M. D.
INDUSTRIA ET LABORE
SUBJECTA MEDICINA
PRUDENTIA ET VIGILANTIA
Elias Gedeler figura.
Mauric Lang sculp.

merely the relics of medieval folklore and superstition. Among them we find **Theriac**, a mixture of numerous ingredients including the flesh of vipers; powdered human skull, parts of birds and lizards; elephant's teeth; horns and genital organs of the stag; oil of scorpions; and intestines of the wolf mixed with myrrh.[6]

Although several of these ingredients were discarded by the 18th century, the pharmacist continued to rely on such components until the emergence of the discipline of pharmacology in the last quarter of the 18th century. One of the earliest attempts to determine on a rational basis the therapeutic action of a plant; to establish in which parts of the plant was concentrated its active principle; and how best to prepare and dispense it to retain its activity, was made by Dr. William Withering of Birmingham who in 1785 published his ten year study of the plant **Digitalis purpurea** under the title of **An Account of the Foxglove.** However, in spite of Withering's endeavours, it took one hundred and fifty years before digitalis came to be employed effectively owing to difficulties of standardisation.[7]

By the early 19th century such active principles as morphine, codeine and atropine were isolated from the crude drug in 1804, 1832 and 1833 respectively; others were synthesised in later years in the laboratory such as salicylic acid (1860), chloral hydate (1869), phenacetin (1888), aspirin (1899) and veronal (barbitone or di-ethyl barbituric acid) (1903).[8]

Patent medicines

The chemical processes involved in the isolation and synthesis of active principles eventually led to the rise and expansion of (a) the patent medicine and (b) the pharmaceutical industry.

The words "patent medicines" originated as a legal term first used in England in 1624 in connection with a law that was enacted to grant monopolies to encourage new industries. Many of the early patent remedies were useless. They were promoted by quacks and charlatans who sold them in the form of powders, lozenges, balsams and tinctures for the relief and "cure" of fevers, gout, renal colic and as nutritional food supplements. Their composition was kept secret but their main ingredients were alcohol, opium, licorice, etc. It was only in the early years of the present century that laws were passed to ensure that the public was not deceived on matters of health such as The Pure Food and Drug Act of the USA.[9]

Fig. 2 opposite page
The frontispiece of the revised pharmacopoeia of John Zwelfer published in Nurimberg in 1675. It is dedicated to King Ferdinand III, Head of the Holy Roman Empire.

The Pharmaceutical Industry

The pharmaceutical industry evolved in Germany and Switzerland at the turn of the century and in Great Britain mostly after the First World War, sometimes with the cooperation and help of research workers in academic circles. Thanks to this development were produced the arsenical compound Atoxyl in 1907, the first effective drug against trypanosomiasis (syphilis and sleeping sickness), Salvarsan (1910) against syphilis, Insulin (1921), for diabetes; Prontosil (1932) against streptococcal infections; Vitamin B^1 (1936); Penicillin (1944); Reserpine (1953); Chlorpromazine (1955) and the hypoglycaemic oral agents (Tolbutamide or Rastinon after 1950).[10]

To give an idea of the progress registered in the production of new synthetic medicaments by the pharmaceutical industry, it has been estimated that of the one hundred-and-fifty drugs most commonly prescribed to-day, only twenty-two were known forty years ago (1946).

On the other hand, these achievements led to the decline in the preparation and dispensing of medicines by the individual pharmacist working alone in his modest shop-cum-laboratory; yet his professional status and his role in the protection and promotion of our health has not diminished or become redundant because the production of new drugs on an industrial scale has not been without adverse effects both economically and healthwise, so that to-day the pharmacist, like the medical practitioner, must be on the alert for dangers arising from overdosage whether accidental or self-induced; interactions between various medicines; side-effects and hypersensitivity reactions; addictive properties; and unexpected harmful manifestations which may occur even after years that the medicament has been on the market and administered to thousands of patients.[11] The phar-

(continued on page 35)

The Quality Control of Non-Sterile Products

Mary Ann Bonanno, B.Pharm.

This is based on the author's B.Pharm. thesis entitled "THE QUALITY CONTROL OF NON-STERILE PRODUCTS PREPARED AT ST. LUKE'S HOSPITAL DISPENSARY".

Introduction

Quality of pharmaceutical products is the sum of all the factors which contribute directly or indirectly to the safety, effecetiveness and acceptability of the product.

Quality to the patient is **fitness for use.** Confidence is important not only for the patient himself but also for all the members of the health profession.

Quality affects also the manufacturer's costs. If there were no defects in the product, quality costs would disappear. However since we are human beings defects do unfortunately exist and costs include:-

a) the preparation and conduction of programs for reaching and improving good quality,
b) selection and control of ingredients and final product including packing and labelling,
c) maintenance of equipment,
d) consumption of products in the destructive tests,
e) testing of products in field storage or in stock to evaluate degradation,
f) keeping detailed records of all stages of manufacture.

Quality factors

Quality is built in the product. Factors to be considered are therefore:—

a) **Personnel** whose background of education, training and experience in manufacturing and control of manufacturing has to be assessed. Employees should know

1) what is supposed to be done,
2) what is being done,
3) knowledge for regulating what is done in a way which will predictably eliminate any non-conformance.

Work must be broken down to well-defined operations and written instructions for every stage be made available. (Fig. 1)

b) **Motivation of personnel.** While training employees particular attention should be given to quality. Communications to employees may be effected by journals or manuals. Complaint letters should be posted with the defect display. Cartoons can be used to get the message across effectively but to a relaxed audience.

c) **Building.** In a hospital especially, demand is unpredictable and if a particular product becomes suddenly very popular and the only possible action is to stretch the resources to the utmost, production sometimes continues under hazardous conditions. Required are the following:-

1) good standards of air filtration, heating and cooling,
2) improvement of room finishes,
3) enclosing of pipework,
4) removal of old woodwork,
5) Proper spacing of machinery and equipment for good, safe operation and cleaning,
6) storage space for batches.

d) **Containers and closures.** Quality, strength, capacity suitability and compliance with standard specifications of closures and container materials must be established. The container, holds and protects the product against physical and adverse environmental conditions like moisture, crushing and light. It presents the product in a convenient quantity and form. Decoration of container informs patient about the identity and purpose of its contents.

Glass is the best standard container material. It is relatively unreactive, strong, easily cleaned, but fragile and heavy. Plastics which are flexible may be preferred for example, in dispensing nasal drops.

However for plastics when used in direct contact with a medicament, the length of time of contact may determine whether problems such as discolouration, leaching and absorption or adsorption of a constituent of the product may arise. Storage conditions, pH, temperature and/or time, surface treatment of plastic container configuration, type of polymer used, method of package preparation and light transmission are also to be considered. The special properties of various available materials must be recognised:- eg. PVC for ointments is resistant to oils but is plasticised by esters like methyl salicylate. Same can be said for polystyrene containers.

Metals are employed in collapsible tubes for semi-solid dermatological preparations. To avoid interaction, internal linings are employed.

Fig. 1

EXAMPLE OF AN EXTEMPORANEOUS PRODUCT WORKSHEET

Type of product: Nose drops	Product Name Ephedrine Nasal drops 1% B.P.C.
Use: to reduce swelling turninate bodies in hay fever, and catarrhal infections	CODE:..... B/N.....

METHOD OF PREPARATION

1. Tare an amber glass bottle at the 100ml volume —
2. Weigh 0.5g **chlorbutol** —
3. Heat about 60ml purified water to 60°C in a conical flask that can be closed later with a glass or polypropylene stopper —
4. Add (2) and insert the stopper —
5. Shake vigorously until solution is complete —
6. Weigh **1g ephedrine hydrochloride** —
7. Weigh **0.5g sodium chloride** —
8. Dissolve (6) and (7) in (5) —
9. Cool, filter if necessary and make to 100mls through the filter —
10. Divide into unit containers —

Preparaed by: Date:	No. of containers filled: Qty. in each: Filled by: Date:

SAMPLE OF LABEL

Labelled by: .....
.....
Date:

PRODUCT CHECKED BY: DATE:

Further notes:
Nasal drops should be supplied in coloured fluted glass bottles fitted with a plastic screw cap incorporating a glass dropper tube fitted with a rubber teat or in a plastic squeeze f bottle fitted with a plastic cap incorporating a dropper device.

Closures give further protection. They should be easily removed and replaced, and should not react with container contents. Any imperfection enhances absorption of water vapour by hygroscopic products. Simplest type is the screw-cap. Also available are press-in and slip-over closures.

e) **Labelling.** Labels should be neatly written to give the patient clear and complete instructions on the use of the preparation and storage conditions. Red printing is used for external preparations. Labels are never attached to closures and should not overlap. They should state clearly the name, amount and strength of the prescribed preparation, directions for use, any relevant warnings, including recommended storage conditions. For small bottles one label should state name, amount and strength of preparation and prescription number. Further important information is stuck at the back.

Only one product is labelled at a time and the exact number of labels are issued to avoid mislabelling of products especially when of different strength.

f) **Equipment.** It is important to have personnel experienced in the techniques necessary for the maintenance of pharmaceutical manufacturing equipment. It should always be cleaned after use. Balances should be calibrated every six months, however daily monitoring against secondary standards is effective.

g) **Specifications for control to guide production.** Manufacture of pharmaceutical products is controlled by the U.S.P., N.F., B.P., B.P.C., which have achieved legal status. They give officially accepted methods of establishing identity, purity and composition of substances in chemical products. They give minimum standards eg. tolerance on percentage active ingredient, minimal sampling plans and standards governing the conduct of an operation. They give also recommendations on containers for dispensing.

h) **Sampling procedures and practices.** These aim at obtaining specimens representative of the constitution and condition of the batch. It could be done in-process and on the product. It gives the opportunity to inspect the materials, containers and labels.

i) **Documentation.** A file is opened for every ingredient to include the certificate of supplier, result of lab analysis, result of test mix which verifies suitability of ingredient in production process. A batch document is also created to include input materials and batch numbers, references to ingredient files, product assays, including initials of every individual associated with every production step from weighing through the release of product by Quality Controller.

Chemical and physical aspect of Quality Control

Chemical, physical and physico-chemical methods of analysis check that the formulated preparations are quantitatively correct and of satisfactory purity at the time of dispensing.

Lately attention has been diverted to a more precise study of the identity and toxicity of likely impurities which influence the safety and stability of the finished product. The procedure then depends on the nature and level of contamination, nature of drug and equipment, istrumentation and time available. Such control implies a large volume of work and it may be preferable to supplement it by inspection of manufacturer's premises and in-process control.

Sources of chemical and mechanical contamination may include:

a) accidental inclusion of dirt, glass, porcelain, metallic and plastic fragments from sieves, equipment and containers, water.
b) incomplete solution of a solute.
c) uneven distribution of suspended matter.
d) insufficient attention to chemical stability of pharmaceutical chemicals and additives under manufacturing conditions.
e) cross-contamination.
f) release of chemicals from product container which influence stability, therapeutic efficacy and safety of product.

Factors affecting quantity of product ingredients are:

a) weighing on dispensing balances,
b) measurement of liquids.

Instrumental Analysis

Analytical information by instrumental analysis gives quick and detailed results besides saving money because the result is expressed faster.

Techniques used extensively in the purity and quantitative determination of a drug are UV-visible spectrophotometry, colourimetry, IR spectroscopy, 'H' nuclear magnetic resonance, acid-base titration, polarography, gas chromatography and HPLC.

The assays given in official guides to chemical analysis are rarely specific. However they are regarded as sufficiently specific when taken

in conjunction with other requirements of the monograph.

Microbiological aspect

An item certified non-sterile is most probably contaminated by microbes. Intensive research in UK has shown that:-

1) Contamination was more common in preparations made or repacked in the hospital pharmaceutical department than in pre-packed commercial products.
2) The heaviest contamination was in distilled, demineralised and peppermint water, other aromatic waters and alkaline suspensions such as mixtures containing magnesium hydroxide or magnesium trisilicate.
3) Aqueous topical creams, peppermint water and alkaline mixtures containing peppermint flavouring were most prone to contamination with **Pseudomonas aeruginosa.**
4) Generally products having a consistently low microbial count are those with a low pH; high sucrose content and a low pH; a low pH and containing benzoic acid; a moderate concentration of chloroform or a high alcohol content.

SOURCES OF MICROBIAL CONTAMINATION

1) RAW MATERIALS
2) PHARMACEUTICAL EQUIPMENT
3) PRODUCTION PROCESS
4) AIR & ENVIRONMENT
5) PERSONNEL
6) CONTAINERS AND CLOSURES FOR PACKING
7) FORMULATION

Raw materials are to be obtained from reliable sources and tested before use. The containers should be opened prior to manufacturing process and checked. Most important is water. Distilled water if not properly collected and stored may harbour bacteria. During storage **P. aeruginosa** can grow in water produced in hospital. Rubber and plastic connections in a still may be sources of infection necessating either frequent sterilisation of the system or the introduction of all-glass equipment. Boiling distilled water immediately before use kills at least organisms like pseudomonas and may be used safely in preparing medicaments at S.L.H.

Consider now pharmaceutical equipment. Production batches remaining in the orifices can form foci for the infection of subsequent batches. Therefore all equipment should be thoroughly cleaned with hot water and detergent immediately after use. It should also be protected from dust during storage.

The production process is also important. Weak points in a production process that may enhance microbial proliferation are: temperature of certain steps and water condensation on the surfaces of ointment or solutions if not allowed to cool before applying closures of final containers.

Walls, floors and ceilings should be smooth and as free as possible from cracks and crevices. Dry sweeping and dusting has to be avoided and replaced by daily swabbing with disinfectant solution. Air supply should be treated to remove most micro-organisms.

The personnel should be trained in hygiene thinking. They should acquire at least elementary knowledge of conditions supporting the growth and dispersal of micro-organisms. They are to wear clean overalls and caps and should be subjected to the same health requirements as are food workers. They should not be employed when suffering from respiratory and skin infections.

If a contaminated formulation is found the assumption is that the contaminent has the ability to adapt or grow in the preservation system. Protection has to be both during and after its preparation. Therefore the efficacy of the preservative has to be evaluated because for example, chloroform can bind itself to powder surfaces in preparations which contain insoluble solids. Such preparations have therefore decreased content of preservative but at the binding site the preservative activity is enhanced.

Conclusion

A manufacturer is responsible for the quality of a product. However, it is very difficult for him to ensure quality when the product is in the hands of the patient.

The importance of training and educating the patient must not be underestimated. Products should be used for their intended purpose as instructed and should be stored for a defined period of time, under appropriate conditions. Such information shoud be clearly given on the label of the preparation.

It is the duty of community and hospital pharmacists to educate the patients and explain the potential hazards of using contaminated products.

Reference:

Bonanno, M.A., *The quality control of non-sterile products prepared at St. Luke's Hospital dispensary*, B.Pharm. Thesis 1986, Pharmacy Department, University of Malta.

Aloe vera Gel

Laurence Zerafa, B.Pharm.

This article is based on the author's 1979 thesis [3] which was aimed at reviewing the present literature on Aloe vera and on a practical aspect try to verify the reports on the curative powers of the plant's fresh mucilage on burnt rabbit skin. A description is given of a method for the preparation of a fresh crude mucilage from fresh Aloe vera leaves, the physical and other characteristics of the Aloe vera gel, and the effect of Aloe vera mucilage on normal and burnt skin.

Introduction

As described in the last issue of the Pharmacist [1] besides the aloes of laxative properties the plant Aloe barbadensis Miller (unofficially Aloe vera Linne) yields from its central fleshy parenchymal tissue a mucilage or gel which although as yet has no officially medicinal status is purported to have beneficial effects on burns and wounds of the skin, and to relieve stomach and duodenal ulcers. These 'recently' discovered effects of Aloe vera gel are well documented in past history and folk uses of this plant. In spite of the popularity of this plant, as yet modern science has not identified the curative agent responsible for the healing powers of the plant proven in man and animal. This fact may explain why the plant bears no official status within medical circles in the western world pharmacopeias.

However, the increase in demand for the leaf and its mucilage, and products derived from it for cosmetic applications has generated widespread interest and research, especially in the USA where the plant thrives well in the Caribbean basin and in southern states like Texas and Arizona. Efforts to establish an official status for the plant and its mucilage has led to the establishment in June 1982 of the National Aloe Science Council (NASC) [2].

A fresh liquid mucilage from Aloe vera leaves

The fresh mucilagenous pulp of A. vera leaf can be applied to the skin in two ways [3].

1. The fresh whole leaf can be split longitudinally and the internal gel side can be applied directly to the skin, or slabs of the gel can be cut to size and again applied to the skin. This corresponds to the NASC definition of RAVG.
2. A liquid mucilage can be prepared by extracting manually or mechanically the internal pulp from the centre of the leaf, dicing it, homogenizing it and then filtering it. This liquid mucilage or gel can be applied directly to the skin or by means of wet dressings This corresponds to the NASC definition of AVG but with no additives or preservatives.

APPROVED DEFINITIONS FOR ALOE VERA LEAF AND PREPARATIONS DERIVED FROM IT:

Among the first jobs of the NASC was to define the nature of Aloe vera products. According to these approved definitions as given by the NASC(4) some of the products of Aloe vera are:

Whole Leaf Aloe vera
Whole Leaf of the Aloe barbadensis Miller-including the rind and internal portions of the plant.

Aloe vera Latex
The bitter yellow liquid contained in the pericyclic tubules of the rind of Aloe barbadensis Mill; the principle constituent of which is Aloin.

Raw Aloe vera Gel (RAVG)
Naturally occurring unprocessed, undiluted parenchymal tissue obtained from the decorticated leaves of A. barbadensis Mill, and to which no other material has been added.

Aloe vera Gel (AVG)
Stabilized Aloe vera Gel — Naturally occurring processed, undiluted, parenchymal tissue obtained from the decorticated leaves of A. barbadensis Mill and to which no more than 5% additives including preservatives, shall have been added as part of the processing.

100% Aloe Vera
Processed, preserved liquid derived from parenchymal tissue obtained from the decorticated leaves of Aloe barbadensis Mill and defined by a value of 1000 using the reporting procedure adopted by the NASC. This Aloe vera gel can be suitably diluted to give **Whole Aloe vera Gel** which contains a minimum of 50% of the natural pulp found in RAVG. **Aloe vera Juice** an ingestable product containing a minimum of 50% AVG. **Aloe Vera Drink** an ingestable product containing less than 50% and more than 10% of AVG and also **Aloe vera Extract**, a dilution of Aloe barbadensis Miller with water or other suitable solvent that contains less than 10% Aloe vera gel and is suitable for ingestion or topical use.

Alternatively the gel may be marketed in a concentrated form. Thus we have:

Aloe vera Concentrate
AVG from which natural water has been mechanically removed and which would have a value of 1500 minimum on the NASC scale.

Aloe vera Gel/Spray Dried
Acquiesce derivative of the leaf of A. barbadensis Miller which has been sprayed dried on a suitable a matrix.

Aloe vera Gel Freeze Dried
AVG which has been freeze dried with or without matrix.

Finally there is **Aloe vera Oil** which is the lipid portion obtained from the leaves of Aloe barbadensis Miller by various solvent extraction processes.

For the experiments described below a liquid mucilage was used for several reasons, which included ease of application, ease of storage and handling and assuming that any healing agents are found intracellularly then homogenization in breaking up the cell walls would liberate any such active ingredients.

The problems with the use of a liquid mucilage are that its production involving several steps is time consuming and, since it involves many steps where it is manually handled, risks of microbial contamination are high and for its intended use the product should be sterile. On a large scale production unit the two problems can be solved by mechanization and use of an aseptic process and use of preservatives.

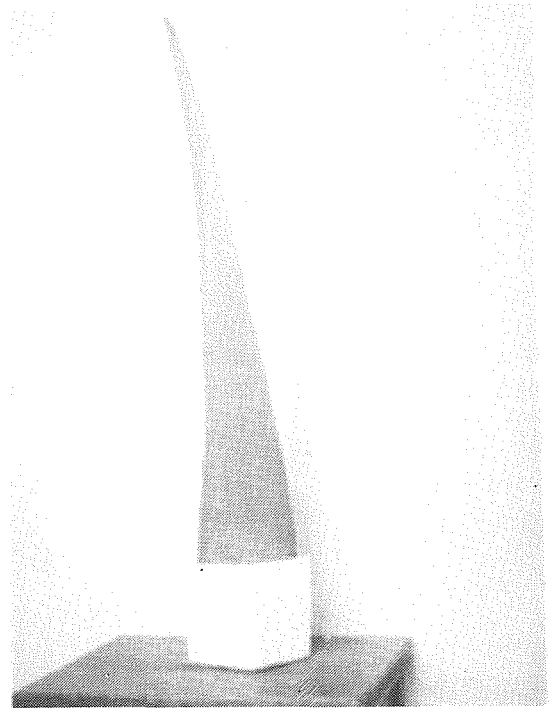
In the small scale production described below the contamination problem was tackled by proper cleaning of all apparatus, containers and working surfaces and use of gloves while handling the leaf and pulp. Finally the liquid preparation was immediately stored at a low temperature below 4°C or frozen at —12°C to eliminate microbial proliferation.

THE SMALL SCALE PRODUCTION OF LIQUID ALOE VERA GEL

The method used involved the following five basic steps.

1. Choosing the leaves
2. Cutting and bleeding the leaves
3. Extraction of the mucilagenous pulp
4. Liquidization of the mucilagenous pulp
5. Removal of cell wall particles.

1. **Choosing the leaves** — leaves from the locally growing A. barbadensis Miller plant were used. The twelve plants chosen growing in the Tal-Qroqq University grounds were of undetermined age but all at the flowering stage. Location varied and none were under any special form of cultivation. The largest, outer most succulent leaves were chosen because of their high yield of gel.
2. **Cutting and bleeding the leaves.** The leaves can be cut neatly at the base with no difficulty. On cutting, the leaves exude a yellowish thick latex from the junction between the outer green rind and the inner white pulp. This latex on drying forms the dark hard solid which is the aloes of laxative properties. To facilitate the drainage of this latex the leaves were held vertically upright overnight, base down over empty containers. This process is known as bleeding and after this process the cut end of the leaf seals itself.



Bleeding the leaves

When not used immediately the leaves could be stored in plastic bags at room temperature in a dark cupboard for up to 3 weeks with only some loss in weight due to minimal evaporation of water and some pink discolouration at the cut end due to formation of oxidation products. When frozen and then thawed the leaves loose their firm consistency rendering further processing impossible.

3. **Extraction of the mucilageneous pulp or RAVG.** The outside surface of the leaf is thoroughly cleaned with tap water and then dried. Of several methods the most efficient one used involved first cutting off the pointed apex and 1 cm from the base of the leaf. The two spiny edges were removed by cutting them away to a depth which just reaches the mucilageneous layer see diagram (1). The flat upper and convex lower surfaces of the leaf were then furrowed longitudinally to a depth which just reaches the mucilageneous layer using a sharp scalpel blade. By inserting the blunt edge of a knife between the two furrows the rind was lifted and peeled away in several strips from both sides of the leaf diagram (1). The appearance of the whole pulp at this stage is a translucent slippery whole mass still retaining the shape of the original leaf.
4. **Liquidization of the mucilageneous pulp.** After cutting into small cubes the pulp could be

liquidized in an electric blender by means of four rotating metal blades at high speed for ten minutes. Liquidization breaks up the cellular structure of the pulp as seen under the microscope diagram (2).

5. **Removal of cell wall particles.** The foam resulting from the homogenization of the pulp was first allowed to break up to form two indistinct layers after two hours, a lower more fluid layer and an upper less fluid layer containing the cellular debris. Centrifugation though effective was not practical and filtration was chosen as the method of use to separate the two layers. Ordinary gauze supported on a Buchner funnel was found adequate to collect the lower liquid layer which on microscopical examination was nearly devoid of particulate matter diagram (2). Methods similar to the one described above are described by other workers in the States, Don L. Smothers[5] and R.C. Benson.[6]

Yield of liquid mucilage — gross analysis shows that the whole leaf yields about 70% of crude solid mucilage while the filtered mucilage is about 65% of the weight of the whole leaf. Considering that leaves on average weigh about 400g this gives an average figure of 260g of liquid mucilage per leaf.

Physical and other characteristics of the Aloe vera gel

The liquid gel so obtained is a white to slightly green translucent liquid. It is slippery to the feel but when well rubbed into the skin it dries up to form a non sticky invisible pliable film which can be washed off easily with soap and water. Various similar preparations are available commercially on the American market.

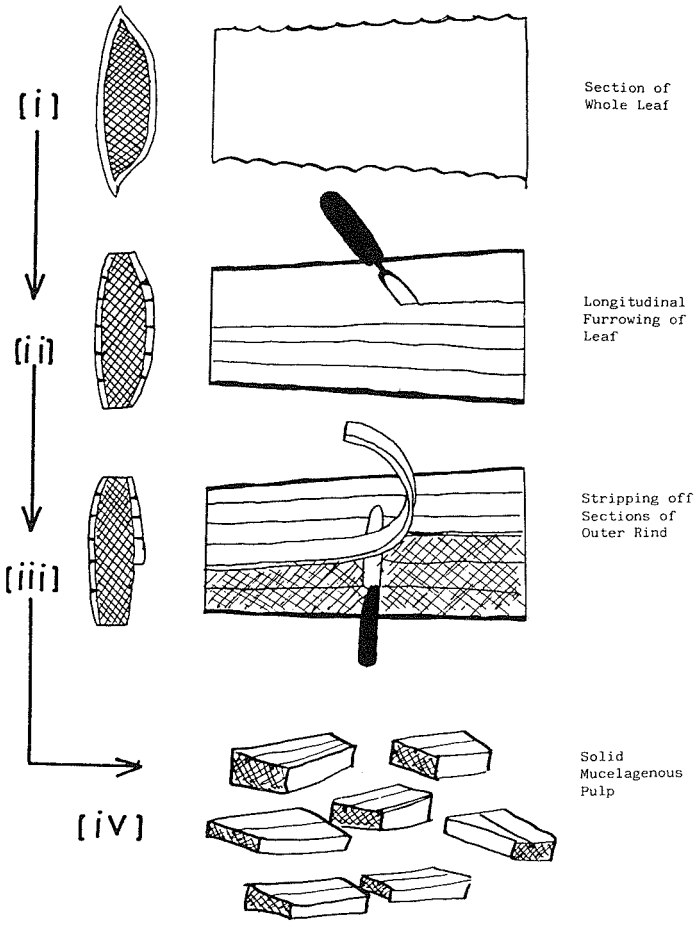


Diagram 1
Extraction of Mucilagenous Pulp from Aloe vera leaves.

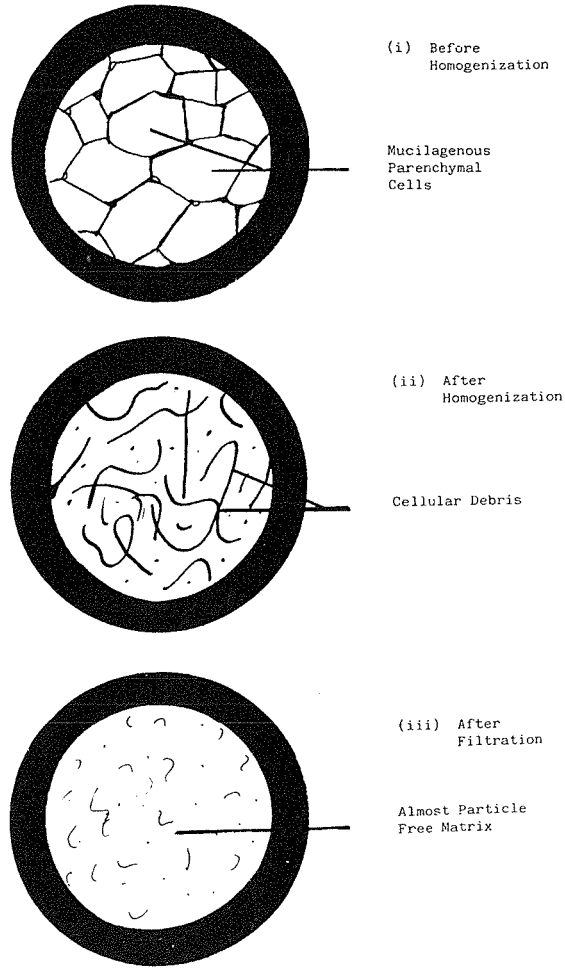


Diagram 2
Microscopical Examination of Aloe vera mucilage.

The physical properties of three commercial preparations is compared below.

a. Aloe vera gel (decolorized). Terry Corporation Florida USA
b. Liquid Aloe vera (single strength filtered) Agrolabs Inc. New York USA
c. Veragel Aloe vera gel (liquid 1:1) Madis Botanical Derivatives New Jersey USA

APPEARANCE — pale to colourless liquid, slightly viscous, clear to slightly hazy a, b, c.
ODOUR — Faint vegetable a, b.
TASTE — Characteristic b.
SPECIFIC GRAVITY — 1.002 — 1.020 a, b, c.
pH — 4.5-6, 3.5-6, 4.5-7.5 a, b, c.
SOLIDS — 0.5-1.2%, 1% max a, b.
SOLUBILITY IN WATER — 100% a, c.
SOLUBILITY IN OTHER SOLVENTS — Soluble in propylene glycol, glycerine (c) Insoluble in alcohol over 20% (higher alcohol content produces white flocculent precipitate) chloroform, acetone, ether and other organic solvents (c).
BOILING POINT — 212°F (a).
TOTAL PLATE COUNT — less than 10 cfu/ml, 50 colonies/g max. less than 500/g a, b, c.
PATHOGENIC BACTERIA — negative a, b, c.
YEAST MOULDS — negative b.
STORAGE — store in a tightly sealed container in a cool place. Refrigeration is recommended once the container has been opened a, b.

In general these properties are similar to each other except for some differences in the pH range which may depend on the type of stabilizers and preservatives added during preparation. The author's preparation when freshly prepared invariably had a pH of 4-4.5 but as was noted no preservatives or stabilizers were ever added.[3]

Other preparations of liquid Aloe vera Gel available commercially are:
a. Aloe vera gel. The Lanaetex Products Inc., New Jersey, USA.
b. Co Vera. Costec Inc., Illinois, USA
c. Aloe vera juice. Chemetics Laboratories Inc., Texas, USA.
d. Aloe vera gel stabilized. Aloe Vera International of Arizona Inc., Arizona, USA.
e. Natural Aloe vera gel. Tri-K Industries Inc., New Jersey, USA
f. Aloe vera (raw). Aloe products Corp., Texas, USA
g. Aloe vera gel. Aloe Laboratories of Texas Inc., Texas, USA.
h. Aloe 11 Aloe vera gel processed. Aloe Vera Scientifics Inc., Arizona, USA.

Stability of Liquid Aloe Vera Gel

This gel unless stored properly or contains preservatives is liable to degradation. The main ways by which degradation of the mucilage can occur are by external microbial contamination (air borne funghi and bacteria) and internal enzymic degradation.[7] The high water content and the protein and calorie content of the fresh mucilae facilitate the growth and multiplication of microorganisms. Degradative enzymes are present within the cellular parenchyma and these are released when the mucilage is produced.

Microbial growth occurs within a week of storing the mucilage in an uncovered container at room temperature. The visible signs of this growth are black patches on the surface with a growth of fine hairs or hyphae extending above the surface. The gel also acquires a characteristical strong smell and very bitter taste. Microbial growth with enzymic effects is also responsible for the depolymerization of the polysaccharide fractions of the gel. This takes place over a longer period. The visible effects are a slow deposition of brown-green particles which settle at the bottom. The consistency of the gel changes from a mucilageneous to a more fluid water solution[3]. This depolymerization of the polysaccharide results in a loss of activity of the mucilage.

Another visible sign of degradation is the change of colour of the gel from colourless (or very light green) to a distinct pink colour. This according to E. Roboz and A.J. Haagen Smit[8] is due to the formation of pink oxidation products which they prevented from being formed by avoiding contact with the air. The rate of formation is increased by heating the mucilage[5].

Microbial contamination and subsequent degradation of the liquid Aloe Vera gel can be reduced or eliminated by freezing the gel as this author did or by the addition of preservatives. Freezing and the addition of stabilizers will minimize the degraditive effects of enzymes on the gel.

EFFECT OF ALOE VERA MUCILAGE ON NORMAL AND BURNT RABBIT SKIN

The object of the series of experiments was to check on a small limited scale whether the mucilage of Aloe vera gel prepared as described above has any harmful or beneficial effects on normal and burnt rabbit skins. The two types of burns used were thermal contact, and U.V. radiation burns.

Animals used. — Ten New Zealand white rabbits were used. They were of undetermined sex, about 3 months old and weighing 2 to 3 kgs. Housing consisted of standard laboratory cages kept in a well ventilated room at room

temperature. Ample food and water were available continuously.

Preparations of rabbits for experiments. — To produce the burns the areas of rabbit skin chosen were the lower back areas for the thermal contact burns and the ears for the UV radiation burns. The areas were first shaved mechanically using scissors and electric hair clippers; the ears completely and about 0.12m² of the whole lower back. Total depilation was achieved using a commercially available depilatory cream. Care was taken to ensure uniformity of treatment of both 4 inch² areas on the back since one ear and one back area was going to serve as a control for the opposite area or ear.

Experimental thermal contact burns. — Of the different methods tried to produce thermal contact burns of deep partial thickness type (see diagram 3) after Whealer[9] which heal spontaneously over a period of about two weeks and hence rate of healing could be observed, the method chosen involved applying as uniform a temperature as possible for a given time. The time-temperature relationship chosen was 58°C for 10 seconds. The setup to produce this temperature is described by diagram 4. A temperature gradient is set up between two ends of a lagged polished brass rod with the temperature of the cold end being monitored by a thermometer inserted inside the brass rod. Once the thermometer end of the rod reached 59°C the burn was produced. With an assistant firmly holding the rabbit the exposed end of the rod was brought into firm contact with a pre-marked area on the rabbit's depilated back for 10 seconds. Immediately after, the brass rod was again applied to the next area nearby. Treatment of one area was started immediately with the other control area receiving no treatment at all. The uniformity of these two burns was confirmed by an approximate same rate of healing when left untreated.

Experimental U.V. radiation burns — For these burns, after both ears of a rabbit had been depilated, the rabbit without any restraint, was irradiated with U.V. light supplied by 2 U.V. lamps placed over the cage. The U.V. lamps emitted light at 254 mm through a 25 cm by 5 cm rectangular opening. Overnight exposure produced moderate sunburn while exposure for a night, a whole day and another night consecutively gave a severe sunburn.

Diagnosis of the degree and depth of burning.

Burns of the skin can be of two types according to the varying depth of the three dimensional thermal injury. Thus, there is

a) a partial thickness burn, and

b) a whole thickness burn Muir[10] 1974

Partial thickness burns may be either superficial (first degree) or deep (second degree). Whole thickness burns may also be referred to as third degree burns, Muir[10] 1974. See diagram (3).

The clinical course of the burn area varies with the type of burn. Whereas partial thickness burns may be expected to heal spontaneously if no complications like infection arise, whole thickness burns require immediate excision and skin grafting for proper treatment Sevitt[11] 1957.

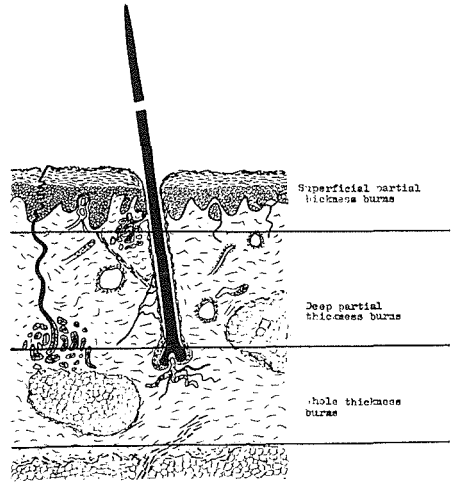


Diagram 3
Depth of burning in relation to structure of the skin. (After Whealer[9])

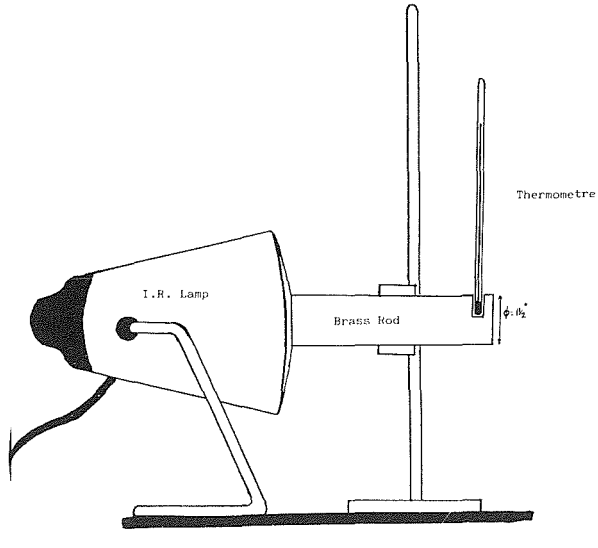


Diagram 4
Apparatus for contact burns

Diagnosis of the depth of burning can be done by testing the sensation in the burned skin (the so called pinprick test) Muir[10] 1974, Jackson[12] 1953 and by examining the surface appearance of the burn Sevitt[11] 1957 and[13]. With these tests it was concluded that none of the contact and radiation burns were of the third degree thickness type. Thermal contact burns had a central area of the second degree type which merged into an outer area of first degree burn. U.V. radiation burns were either mild or severe depending on duration of exposure 16 hours or 40 hours consecutively. None were third degree and distinction between first degree and second degree was less distinct.

Treatment.

The only line of treatment used was the liquid mucilage of Aloe vera prepared as described above. Prior to actual use the mucilage was warmed to room temperature after storage at 4°C or at —12°C. The mucilage was applied by means of dressings held over the burn or else a piece of cotton wool was wetted with the liquid mucilage and then massaged over the burn after which it was allowed to dry to form an invisible pliable film. In between applications the treated area or ear, as well as the untreated back area or ear were not washed or cleaned of any wound debris.

Treatment was applied daily except Saturday and Sunday, for a period up to three weeks but usually only for a few days. Number of applications per day varied from a minimum of three applications with the dressings to a much higher frequency when no dressings were used. Unless a dressing was applied no treatment was applied between 4.30 p.m. and 8.30 a.m.

Observations, records and deductions from course of healing

Observations were made prior to each application. With normal skin, recordings were made on how long it took for normal hair regrowth to take place, with bruised skin how long it took for bruises to dry up and hair regrowth to take place. With second degree burns how long it took to form a thick eschar, for this eschar to separate, the appearance of this granulation tissue, when granulation tissue was no longer visible and how long it took for normal hair regrowth to occur.

With U.V. radiation the degree of redness, the formation, duration and separation of any hard eschars and time taken for subsequent hair regrowth to occur were noted

The final normal hair regrowth was taken as a sure sign that the area had healed completely.

Experiments and results

The effect of liquid Aloe vera gel or mucilage on normal depilated and burnt skin of a small number of rabbits can be summarised as follows:

i. on normal depilated skin — of four areas treated all areas showed an initial more rapid hair regrowth when compared to control areas. After a few days this effect was no longer apparent.

ii. on first degree contact burn — only one area was treated and this showed that when its crust has fallen off, hair growth occurred at an earlier stage when compared to the control area. Within a few days there were no differences between treated and untreated areas.

iii. on second degree contact burns — of four areas treated all showed darker crust formation which was discarded at an earlier stage and hair growth over the treated areas proceeded at a faster rate in the initial stages of regeneration.

iv. on U.V. radiation burns, three areas were treated. The mucilage showed no apparent effect on the latent effects of the radiation but when healing started the mucilage had an effect on crust formation which was thicker and was discarded at an earlier stage in the aloe treated area. Hair growth also occurred at an earlier stage.

In all cases treated there were no cases of irritation and none of the areas treated with aloe mucilage showed any worsening of the conditions.

Conclusion

These results show that the mucilage of Aloe vera does have a beneficial effect on the initial regenerative stages of normal depilated, burnt and bruised rabbit skin.

Hair growth occurs at an earlier stage in these areas. If hair growth is assumed to be a clear indication that healing is proceeding than the mucilage of Aloe vera has a healing action on bruised and burnt skin.

The results confirm the beneficial effects of Aloe vera mucilage as described by other workers such as Rowe T.D.[14] 1940, Rowe T.D. et al[15] 1941 who experimented with the use of the fresh pulp of the leaf in the treatment of experimentally produced third degree X-ray reactions on the skin of white rats, C.C. Lush-

(continued from page 23)

macist, thanks to his/her direct personal relationship with the patient or relatives is in an ideal position to bring the above risks to the knowledge of the client and to tender the necessary cautions and advice.

In this context I would suggest that with the traditional mortar and pestle, as the emblems of the art and science of pharmacy, be incorporated the word VIGILO as the motto of the modern pharmacist.

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baugh and B.B. Hale[16] 1953 who worked with rabbits which were subjected to experimentally induced acute radiodermatitis by radiating locally the shaved backs with 11,000 and 28,000 rep of beta radiation from Sr^{90}, Rovatti and Brennan[17] 1959 who used rabbits subjected to thermal contact burns with a hot steel plate and Goff and Levenstein[18] 1964 who carried out carefully controlled experiments where they measured the effects of topical preparations including Aloe vera extract upon the healing of skin incision wounds using measurements of the tensile strength of the healing wound as indication of rate of healing. In all these cases results showed that aloe vera pulp, mucilage on preparations derived from it have a beneficial effect on the healing of these different types of skin wounds.

Though the author's results confirm the beneficial healing effect of Aloe vera mucilage they are far from being statistically significant on their own. The number of areas treated was too few and only description rather than photographic evidence is presented. Whenever possible any difference between treated and untreated area were confirmed by colleagues.

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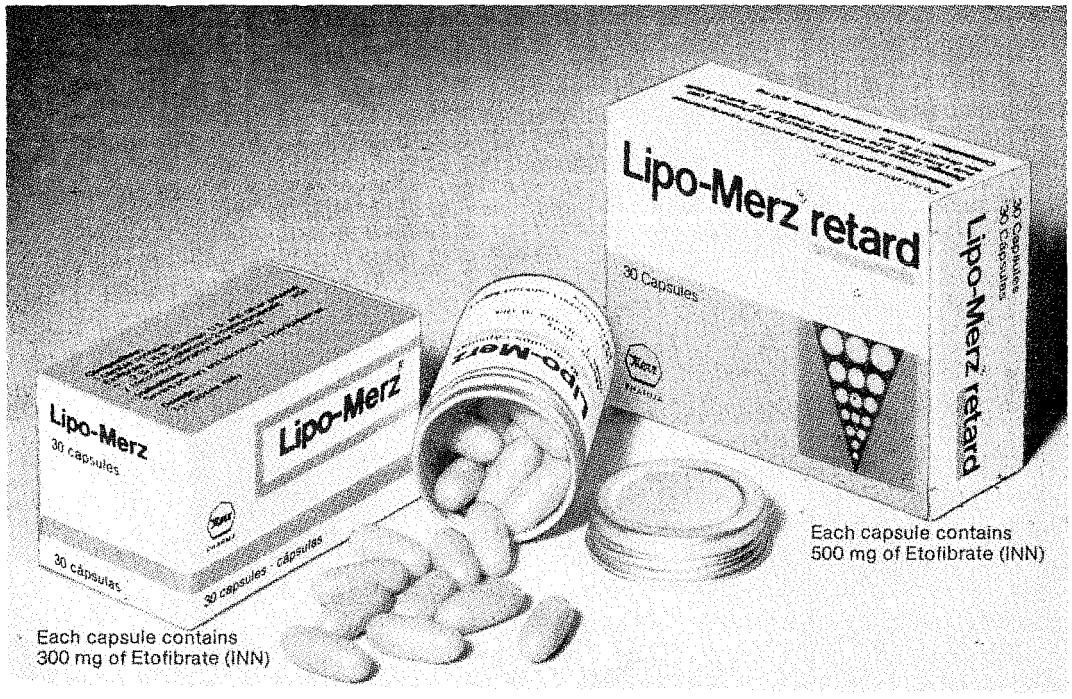

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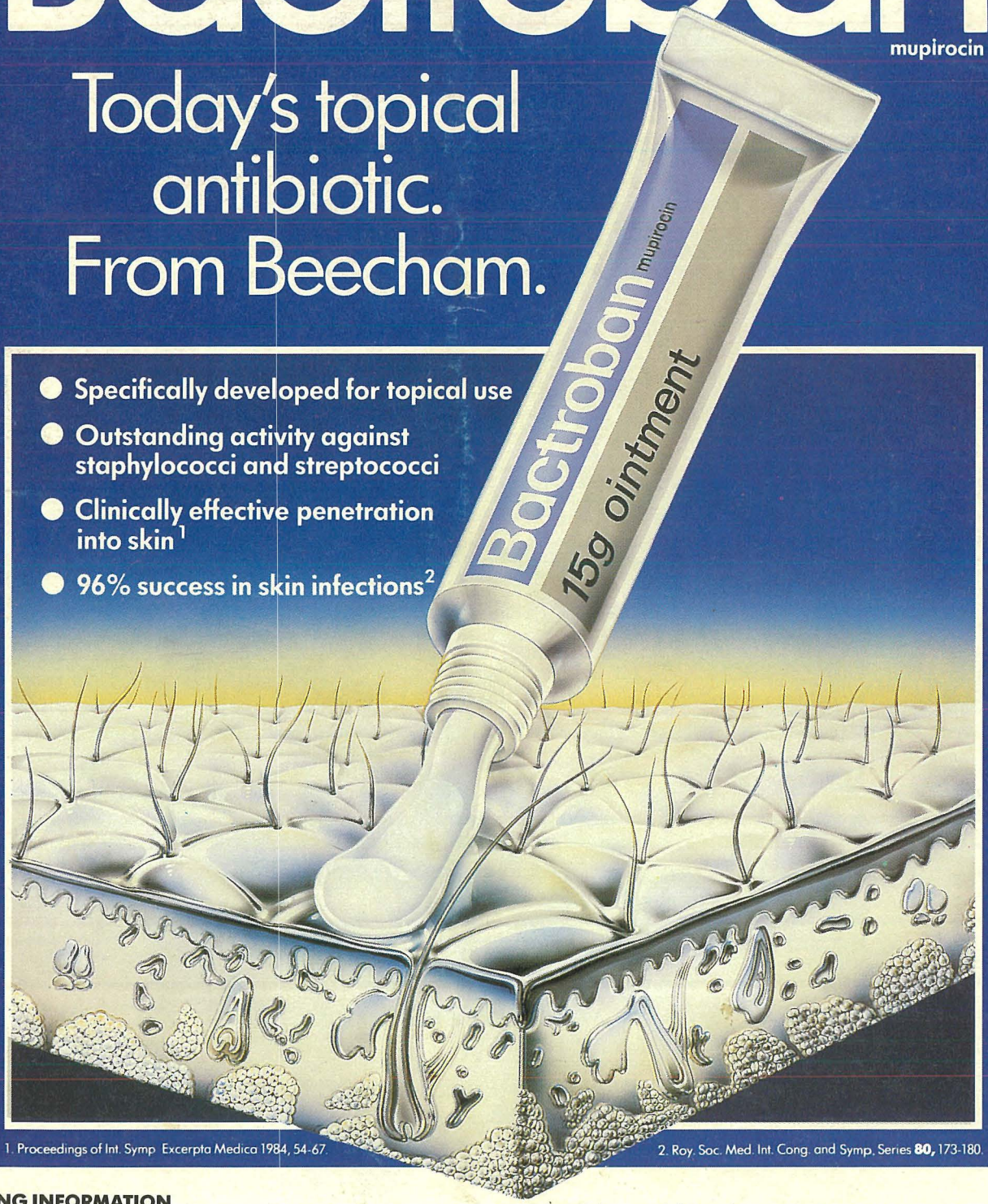

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