フィリピン国食品医薬品検定センタープロジェクト

巡回指導調査団報告書

1990年9月

国際協力事業団

医療協力部

序　　文

本プロジェクトは，フィリピン共和国食品医薬品局（ Bureau of Food and Drugs, Ministry of Health ）の強化を通じて同国における食品・医薬品の品質と安全性を確保し，同国国民の健康に資することを目的として，昭和６１年７月から５年間の予定で開始された。

当事業団は，これまでの技術協力内容の調査・評価と，平成元年度の具体的な協力計画について，フィリピン側と協議するため，昭和６３年１２月１日から１２月９日まで，小野宏㈶食品薬品安全センター秦野研究所副所長を団長とする巡回指導調査団を派遣した。

本報告書はその調査結果をとりまとめたものである。ここに，調査団各位，ならびに調査団派遣にご協力を賜った関係機関の各位に対し深甚なる謝意を表する次第である。

平成元年３月

国際協力事業団

医療協力部長　近藤　健文

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国家医薬品政策（The National Drug Policy）関係資料

1. 巡回指導調査団の派遣

1.1 調査団派遣の経緯と目的

(1) プロジェクトの概要および経緯

① 名　称

和文：フィリピン国食品医薬品検定センタープロジェクト

英文：The Food and Drugs Laboratories Project

② R／D署名日：昭和61年7月25日

③ 協力期間：昭和61年7月25日～平成3年7月24日

④ フィリピン側関係機関：保険省食品医薬品局〔BFAD〕

(Bureau of Food and Drugs, Pepartment of Health)

⑤ 日本側協力機関：㈱食品薬品安全センター

厚生省

国立衛生試験所

大阪府環境保険部薬務課

⑥ 経緯：フィリピン国における食品医薬品検定業務は，BFADにより実施されているところ，近年のめざましい食品・医薬品産業の発展を背景に，国民の健康に密接に結びつく食品・医薬品の品質と安全確保についての政策促進のため，わが国へ技術協力（および関連施設建設に係る無償資金協力）要請越した。

これに対して我が方は，60年1月の事前調査団，61年7月の実施協議調査団派遣により，以下の各分野につきプロジェクト方式技術協力を開始した。①実験動物の飼育管理，②動物実験，③微生物学，④食品理化学分析，⑤医薬品理化学分析，⑥監視審査

無償資金協力によるBFAD新実験棟も昭和62年4月に開所され各分野での本格的な技術移転が進行しているところである。

(2) 調査団派遣の目的

昭和61年度における技術協力の動きは，R／Dが年度半ばに署名されたこともあり，比側による各種要請書の提出作業・日本側における詳細の協力計画の詰め作業についやされたが，62年度に入ってからBFADの開所に合わせ長期専門家を派遣し，実質的な技術移転がスタートした。昭和62年12月に，計画打合わせ調査団を派遣し，技術協力進捗に伴う協力実施計画の見直し・調査を行ったところであるが，本年度はプロジェクトの中間年度にあたり，これまでのプロジェクト進捗状況の確認・詳細と，今後（特に平成元年度）の協力計画を，フィリピン側と協議のうえ策定することを目的として調査団を派遣する。

(3) 調査事項

① プロジェクト進捗状況の確認と評価

・プロジェクト全体および分野別の活動状況および目標達成度

・専門家派遣の成果および問題点（移転技術の定着と応用）

・研修員受入れの成果および問題点（定着性，知識・技術の応用）

・機材供与の成果および問題点（活用とメインテナンスの状況）

・両国の実施体制

② 平成元年度実施計画の策定

・専門家派遣

・研修員受入れ

・機材供与

(4) 調査方法

① 施設（ＢＦＡＤ）の視察

② 比側カウンターパートとの面談

③ 派遣仲専門家との面談

④ 比側責任者との協議

1.2 調査団の構成

団長：小野　宏（動物飼育管理・微生物および総括）

㈶食品薬品安全センター秦野研究所副所長

団員：義平　邦利（食品理化学分析）

国立衛生試験所食品添加物部長

団員：武田　寧（医薬品理化学分析）

国立衛生試験所薬品部長

団員：高谷　幸（食品・医薬品監視審査）

厚生省生活衛生局食品保健課衛生専門官

団員：江頭　栄二（企画協力）

国際協力事業団医療協力部医療協力課職員

1.3　調査日程

日時	年　月　日	曜日	
1	63. 12. 1	木	10：20　東京（成田）発－（JL-741）→14：00マニラ着 17：00　氏家リーダー，田坂調整員，鈴木専門家と調整日程打合せおよび国内委員会の決議事項につき現地専門家チームへ説明
2	12. 2	金	9：30　ＪＩＣＡフィリピン事務所表敬 宮本所長，小澤職員に調査方針説明 10：00　日本大使館表敬 ・岡本書記官より National Drug Policy の説明 ・ＢＦＡＤは毎日のように新聞にも載り，比国内でも注目されている旨の報告 11：00　National Economic Development Authority(ＮＥＤＡ)表敬 Dr. Cabanos に対し調査方針説明 ＢＦＡＤに予算と人員が不足している旨報告あり 13：45　保健省Ｄ．Ｏ．Ｐ（Department of Health）表敬 Dr. Mario M. Taguiwalo と Ｂ．Ｆ．Ａ．Ｄの機能役割につき協議 15：30　ＢＦＡＤ訪問・視察 ・Sanchez 局長不在の為，Alba 検査部長Castillo総務部長に表敬および調査日程打ち合わせ ・小川衆議院議員ＢＦＡＤ視察のため宮本フィリピン事務所長，氏家リーダー，田坂調査員が案内
3	12. 3	土	10：00　田坂調査員宅にて日本側打ち合わせ 調査団，氏家リーダー，田坂調査員，中曽専門家，鈴木専門家，尾川専門家で調査方針および調査内容につき事前協議
4	12. 4	日	資料整理，調査団内打ち合わせ
5	12. 5	月	9：00　第１回協議（於：ＢＦＡＤ） Sanchez 局長，Castill 総務部長，Alcala 製品審査部長，Barros 監視第１部長，Alcantara 監視第２部長，

			Alba検査部長の他 Advisory Committee for ＢＦＡＤの Dr. Cecile Gonzales, Pro. Loficia B.Gufierrez, Dra. Natividad de Castro の３委員が出席 9：30 氏家リーダー，中曽専門家の案内により，ＢＦＡＤの活動状況視察 13：30 第２回協議（於：ＢＦＡＤ） ・比側よりこれまでのプロジェクトの評価，今後の協力内容について要望 ・日本側より，プロジェクトの進捗状況・今後の協力計画につき説明 17：30・比側より出された要望につき調査団内打ち合わせ
6	12. 6	火	8：40 ＢＦＡＤ訪問 9：00 第３回協議（於：ＢＦＡＤ） 平成元年度協力計画について全体協議を行った後，計画の詳細について部門別協議 ①実験動物，微生物および抗生物質部門 小野団長，中曽専門家，Gutierrez 獣医，Salazar 抗生物質室長，Dy微生物室長 ②食品部門 義平団員，鈴木専門家，Lucero 食品室長，Martin 毒性室長 ③薬品部門 武田団員，Elvena 薬品室長，Lorenzo 化粧品室長 ④監視審査部門 高谷団員，Barros 監視第１部長，Alcantara 監視第２部長 ⑤運営管理部門 江頭団員，Castillo 総務部長
7	12. 7	水	9：00 第４回協議（於：ＢＦＡＤ） これまでの総括およびミニッシ（案）協議 13：00 各検査室長と調査団により，プロジェクトの問題点につき意見交換

8	12. 8	木	9：00 第５回協議（於：ＢＦＡＤ） Sanchez 局長，Alba 検査部長部長，Alcala 調査部長 Barros監視第１部長，Alcantara 監視第２部長，調査団 氏家リーダー，田坂調査員，中曽専門家，鈴木専門家， 大島ＪＩＣＡフィリピン事務所次長，小澤職員ら出席の もとで総括全体協議の後ミニッツ署名 10：00 大島次長，小澤職員へ調査結果報告 14：50 武田団員帰国（マニラ発） 19：30 岡本書記官へ調査結果報告
9	12. 9	金	14：50 調査団マニラ発 19：40 東京（成田）着

1.4 主要面談者

＜フィリピン側＞

(National Economic Development Authority)	
Staff, Social Development	Dr. Cabacos
	Ms. Fleur de lys Torres
(Department of Health)	
Undersecretary of Health	Mr. Mario M. Taguiwalo
& Chief of Staff	
Chief, Foreign Assistance	Dr. Linda L. Milan
Coordination Service	
(Bureau of Food and Drugs)	
Director	Mrs. Catalina C. Sanchez
Head, Legal Information	
& Compliance Division	Atty. Lorna Frances Cabanlas
Head, Administrative Division	Mr. Rodrigo A. Castillo
Head, Produst Evaluation Division	Ms. Juliet Alcala
Head, Regulation Division I	Ms. Virginia O. Barros
Head, Regulation Division II	Ms. Teodra N. Alcantara
Head, Laboratory Service Division	Ms. Ofelia M. Alba
Physico − Chemical Section	
・Chief, Drug	Ms. Blisea Blvena

・Chief, Food	Ms. Josefa Lucero
・Chief, Antibiotics	Ms. Alicia Salazar
・Chief, Cosmetics／ＨＨＳ	Ms. Alicia Lorenzo
Chief, Research Section	Ms. Carmina Parce
Chief, Microbiology Section	Ms. Isabel Dy
・Chief, Toxicology	Ms. Rosario Martin
Chief, Experimental Animal Section	Dr. Oscat Gutierrez
(Advisory Committee for BFAD)	
	Dr. Cecile Gonzales
	Prof. Loficia B. Gufierres
	Dra. Natividad de Castro

＜日本側＞

（食品医薬品検定センタープロジェクト派遣中専門家）	
チームリーダー	氏家　淳雄
調整員	田坂　　厚
動物飼育管理専門家	中曽　正次
食品分析専門家	鈴木　　隆
微生物学専門家	高島　浩介
生物検定毒性試験専門家	尾川　伸之
食品監視審査専門家	酒井　　悟
医薬品監視審査専門家	柚木　茂喜
〃	山本　文雄
（ＪＩＣＡフィリピン事務所）	
所　長	宮本　守也
次　長	大島　勝彦
副参事	小澤　勝彦
（在日フィリピン日本大使館）	
２等書記官	岡本　浩二

2. 総　　括

1986年７月に開始された本プロジェクトは，現在２年半を経過し，ちょうど計画の中間時点に達したことになる。今回の調査で，プロジェクトは総じて順調に展開していることが確認された。

調査団は日本大使館，フィリピン国経済企画庁(ＮＥＤＡ)，保健省への表敬訪問の中で，現在フィリピン政府が推進している医薬品製作（National Drug Policy）について知る機会を得た。本政策によってＢＦＡＤに課される業務はきわめて重要なものと考えられ，ＢＦＡＤの活動はこの政策の影響で拡大充実を強いられることは必至であろう。それは当然，本プロジェクトの展開にも影響が大きい。この事は，この新しい課題にＢＦＡＤは全力をあげて取組みつつあると見てとれた。技術協力体制としても当初の計画の範囲を逸脱しないようにしがらも，ＢＦＡＤの現在と近い将来のためにも最も効果的な協力の方針をとれるように意図すべきであろう。

プロジェクトの現状および次年度の計画に関するＢＦＡＤスタッフとの協議は順調に進行した。

今回新たに比側から要求されたこととして，上水処理設備の改造，動物飼育施設空気取入れ口のＨＥＰＡフィルター，さらには建物の増設があるが，その必要性，緊急性については今後更なる検討を要するものである。

3. 暫定実施計画の進捗状況

3.1 動物飼育・管理部門（ EXPERIMENTAL ANIMAL SECTION ）

動物飼育室では現在マウス・ラットおよびウサギの飼育・繁殖，ならびにこれらのための飼料の自家製造も行っており，動物の生育状況は順調である。動物を用いた実験は小規模ながら開始され，またネコを用いるヒスタミン試験が実施開始された。なお，コンベンショナルのウサギを用いた発熱性試験も実験室内で行われている。

1988年4月に輸送して飼育を開始したマウスおよびラットの飼育は順調に行われ，現在それぞれ約 650匹ずつ飼育観察中である。飼育スペースと経済性を考慮して現在生産調整を行っているが，月産 500匹程度の供給は可能と思われる。

これらの動物を用いる実験の実施は当初の計画ではもっと後に予定していたためまだ本格化しておらず，今年フィリピンで大発生した赤潮のプランクトン毒の検査（マウスに投与した時の急性中毒死に至るまでの時間を測定するもの）に用いたり，外部機関に提供したりしているが，動物の消費はまだ僅少である。すなわち，本格的な動物実験の実施を待っている状況である。

ウサギは発熱性試験実施の要請が強いため，予定を早めて1988年10月に輸送し，飼育を開始した。現在繁殖中である。この試験は比側の要望が大きいため，現地産のコンベンショナルウサギを用いて実験が開始された。最初は屋外の別棟（建設飯場跡）を用いて行われたが，空調された施設でないと成績が不安定であるという理由で，本施設の実験室を使用するに至った。この処置は，動物飼育繁殖の機能に及ぼす悪影響が憂慮されるが，飼育側との交通を完全に遮断することで対処されており，現状では格別の支障は認められない。ただし，今後清浄なウサギの繁殖供給が可能になった時点でのこの実験室の清浄化には多大の努力が必要となろう。なお，ウサギの需要に応じるため当初予定した繁殖室のみでは不足なので，飼育室も繁殖に利用し，成長したウサギの飼育は実験区域のストックルームで行いたいとの比側意向があり，機材が整備されるまで刺激性試験用実験室をウサギ飼育室に使用するという案があり，現実的なものと認め，合意した。

動物飼育施設の環境条件についてはいくつかの問題が提起された。

① 上水処理システム：既に派遣中専門家から報告があったが，処理法の経費すなわち，メインテナンスの費用の問題がある。これは技術的（工学的）に経費節約の面からの検討が必要なので，早急に手続をとるよう比側に勧めた。

② 空調関係：ⓐ空気取り入れ口にＨＥＰＡフィルターが取りつけられていないため，その必要性を検討する。ⓑ動物飼育の開始とともに室内の粉塵の発生が増加し，その再循環を防ぐため，飼育室の排気口にフィルターを取り付けた必要が生じたが，その処置によって室内の気圧が高まり，汚染廊下との差圧が高まるとともに，清浄廊下との間に逆差圧が生

じる。これに対処する必要性とともに，排気用の換気扇を取りつける必要を検討する。

ⓒ湿度調整：湿度の自動調整システムは運転経費負担の考慮から設置されなかったが，実測によれば，きわめて高い値を示すことがしばしばあり，動物飼育環境としては適当と思われない。そこで必要な室ごとに除湿機を配置して湿度調節が可能なように計画した。

③ 動物の侵入：これまでも問題にされていたようにヤモリの侵入はなかなか防げない。ただし，アリは薬剤の使用によりほぼ完全に駆除された。

④ 飼料の製造：現地で入手できる材料を用いてマウス・ラット用とウサギ用の固型飼料を製造している。材料の穀粉には，コクゾウムシのような昆虫が混入している事がある，これは低価格のものである為やむを得ないものであるとのことであった。最終的に熱処理を行うのであまり大きな影響はないと考えられる。

⑤ 今後動物実験とくに毒性試験を実施して行くには現在のスペースでは十分でなくなる可能性が考えられる。元来，本館に“Toxicology”として1室予定していたが，ＢＦＡＤ組織の改革で，Experimental Animal Section とは別に Toxicology Section が新設され，この部屋を使用している。現在の業務内容は，動物毒性試験には関係のない農薬等の化学試験である。

毒性試験に関連して，解剖室のほかに血液学，血液化学，尿，および病理学的検査のための場所が必要になる。当面，解剖室の多角的利用，検体調整室の利用で対処することができると考えられる。ただし，検体調整室は前回調査団の指摘にもある通り空調が必要である。

現在，派遣中の動物飼育・管理，中曽専門家は，動物飼育管理室の諸問題をよく把握し，現場でできる限りの対応をとっている。ＢＦＡＤ側職員への指導も行き届いており，施設内は適切に整頓されている。

とくに，彼はタガログ語による会話ができることは有利である。現在実験動物の繁殖・育成は順調に行われているが，この成否は継代をくり返してみないと判断できない。また，動物の健康状態の判定は体重の推移と外観のみで行われているが，各種の検査を加える必要があり，今後に残された業務も多い。動物の微生物学的統御の検査も未だ実施されておらず，今後の課題である。動物実験の指導のため短期派遣された尾川専門家は，調査団と同時期に滞比していたが，成功裡にヒスタミン試験の技術移転を行った。ポリグラフの運転は業者から機材据付け技術の派遣を得て据付けが行われたのできわめて順調に進行した。当分は血圧測定実験に限って行うように配線を固定しておくこととし，その他の実験への応用（たとえば，摘出平滑筋標本を用いるオキシトンの検定など）は後日対応することを考慮した。ネコは野放しのものを捕獲してあり，比較的容易に入手できる模様である，暫時飼育も問題なく行われていた。比側はコンベンショナル動物飼育についてはかなりの技術を持っていると考えられる。動物実験のＢＦＡＤ側カウンターパートは Mr. Oscar Gutierrezである。彼の努

力によって，ヒスタミン試験は実施可能となった。彼は動物飼育管理の研修を日本で受けており，これが有効に活かされたようである。ヒスタミン試験等動物実験の研修を受けた Ms. Dory Duranは現在薬品理化学研究室に所属し，動物実験は行っていない。しかし，彼女の研修は動物実験を理解するという点では有益であったと評価することができる。最近生起したある薬品（鎮咳薬テキストロメトルファン）製剤による中毒事故（嘔吐などの神経症状）に関する動物実験成績の紹介を受け，若干検討した。また Mr. Oscar Gutierrezの立場は現在動物飼育管理の監督にあり，ＳＰＦ動物の飼育作業に直接は係わっていない。その点では，日本における研修結果が直接生かされているとは言えないが，それぞれ発展的に業務に当っていると解することができる。

3.2　微生物部門（ MICROBIOLOGY SECTION ）

ＢＦＡＤの微生物部門の業務は主として食品と薬品の微生物汚染の検査であり，長年の経験によって作業は円滑にすすめられているが，内容は比較的簡単で，菌の検出の有無を調べる程度であり，その同定などには及んでいないようである。また，以前医薬品微生物室と称されていた部局は抗生物質室となり，抗生物質の力価検定を行っている。この部門には電子顕微鏡が供与され，高島専門家の指導により運転可能となっている。これには，日本で研修を行った Ms. Carmina Parceが当っているが，電顕操作法を修得していた。なお，彼女は現在，Research Sectionの所属になっておりこの課は，問題の発生に緊急に即応して当る課題を負った部局であり，多才な人材が要求される課である。Ms. Porce はその要求をよくこなしているようである。彼女はその業務の他に，微生物学的業務を実施している。

3.3　食品理化学分析部門（ FOOD SECTION ）

この部門は，現在職員14名で，主な業務は食品の栄養成分を中心とした各種の成分分析と食品用着色料の検査である。これらの業務の遂行には，わが国に於ける研修員の受け入れおよび鈴木専門家，柴田専門家，柴崎専門家等の派遣による技術移転と，供与された施設，機器，器具等が有効に利用され，多大な貢献をしている。Section 内はこれらの技術，施設，機器，器具等の充実により活性化がみとめられ，３年前に訪れた旧研究所と比較すると隔世の感であった。1988年１月から11月までの検体処理数は 4,929件で，試験項目は21,175にも上り，この点からも本プロジェクトは成果を挙げつつあるものと思われる。現在行われている主な業務内容を以下に示す。

A　業務内容

①　穀物製食品及びパン製品：表示に基づく脂肪，蛋白，灰分，繊維，ビタミンＡ，Ｂ，Ｃ，水分等の検査と着色料の検査

② 牛乳及び乳製品：表示されたビタミン類とミネラルの検査
③ 肉及び肉製品：硝酸，亜硝酸及びでんぷん類の検査
④ ピーナッツ製品：アフラトキシンの検査
⑤ 脂肪及びオイル：ヨード価，過酸価，ケン価，酸価，屈折率の試験
⑥ 調味料：表示のタンパク質，塩及び着色料の検査
⑦ 砂糖製品及び蜂蜜：グルコース，シュクロース，灰分，プロリン，水分等の検査
⑧ 瓶詰め果物等：表示に基づく着色料，糖，pH及び水分活性の検査
⑨ アルコール性飲料：メタノールとエタノール以外のアルコールの検出と表示に基づくエタノール含量の検査
⑩ 健康食品：ビタミン類及びミネラルの検査
⑪ 麺類：ホウ酸と着色料の試験
⑫ 海産物：乾燥海産物はホルマリン；貝は貝毒のバイオアッセイ；缶詰はＴＬＣとＵＶを用いたヒスタミン試験
⑬ 食品用着色料：規格基準作成のための定性定量試験
⑭ 消費者の依頼試験：ビタミン類の試験

B 職員の業務分担

試験検査が多種多様にわたり，年間を通じて対象品目が一定しないために担当者と対象品目は固定化していないが，主なものは次のとおりである。

① Josefa P. Lucero：マネージメント
② Gloris P. Tomboc：苦情がでた各種食品，健康食品，牛乳及び乳製品の成分検査
③ Ma. Fely M. Senfelices：缶詰，穀類製品，ココナツ製品，乳製品及び瓶詰の粗悪品と不当表示に関する検査
④ Rossana R. Peralta：R.A. 3720 に基づく果物ジュース，果汁飲料及び濃縮ジュースに関する検査；茶及び茶製品中のアルカロイド含量の検査；企業家らの依頼試験；牛乳及び乳製品のビタミン類の含量検査
⑤ Purificacion C. De Guzman：ナッツ，ナッツ製品殻類及びコーン製品中のアフラトキシン；アフラトキシンの検出に必要な試薬の作成；脂肪と油の検査
⑥ Thelma D. Rosario：R.A. 3720 による各種酢の検査；各種ワイン及びアルコール飲料の検査
⑦ Ma. Victoria B. Pabrua：R.A. 3720 に基づく麺類，瓶詰の検査及び各種缶詰の内容重量の検査；食品検査に必要な試薬の調整と作製；魚醤油及び醤油中の蛋白質の検出
⑧ Felicisima R. Alipio：瓶詰製品の粗悪品，不当表示に関する検査R.A. 3720 に基づく各種麺類の検査，食品中の食品添加物着色量の検査

⑨ Elvira E. Nano：各種肉製品，スパイス，ミックス食品及び海産物の試験

⑩ Lourdes A. Cruz：研究補助

⑪ Nornan A. Henson：研究補助

⑫ Virginta D. Garcis：各種瓶詰，調味料，酢，果汁及び海産物の試験

⑬ Leny P. Macawile：試験検査結果の整理

⑭ Cathertine P. Cruze：アルコール飲料，輸出食品等の試験

3.4 毒性部門（ TOXICOLOGY SECTION ）

このSection は既に3年前には組織としては存在していたが，最近業務分担が一新され，現在は化学的手法を用いて，食品添加物，食品及び医療用容器包装等の試験検査を行っている。1988年1月から11月までの試験検査件数は 1,007で，試験項目は 3,893である。業務内容を下に示す。

業務内容は，ほぼ業種別に担当者が決まっている。

業務内容：

① 食品，加工食品，医薬品，ミネラルウォータ中の重金属及び不純物の検査

担当者：Amelita P. Manalansan
Marilou U. Martinez
Amado M. Ong

② 食品及び医薬品の製造に用いられる化学物質の品質確保に関する試験

a) 食品添加物規格に関する試験

担当者：Amelita P. Manalansan
Marilou U. Martinez

③ 直接及び間接的に添加した食品添加物の適合性の検討

担当者：Amelita P. Manalansan
Marilou U. Martinez

④ 食品及び医薬品に用いられる容器包装に関する試験

a) 食品及び加工食品用プラスチック

b) 輸液用プラスチック容器

c) コーティング剤

d) 乾燥食品用包装

e) 木製コップ，皿，容器等

f) 食器類

担当者：Rosario E. Martin
Amado M. Ong

⑤ 医療用具

担当者：Rosario B. Martin

Amado M. Ong

⑥ 食品及び加工食品中の残留農薬（技術研修中で業務は行っていない）

担当者：Rosario B. Martin

現状では，ＢＦＡＤには，残留農薬を実際に取り扱うSection はなく，試験検査を業務を行っていないが，Toxicology Sectionで鈴木専門家が新たに残留農薬についての技術移転を行いつつあり，また昭和63年度の計画で，国立衛生試験所食品部で平成元年３月より６ケ月研修員を受け入れることになっているので，１年後には，このSection の中で残留農薬の試験検査業務が可能となるものと期待される。

容器包装に関しては，容器包装の材質検査は行っているが，溶出試験等は行ってない。今後，わが国での研修，専門家による指導により一段と業務内容の充実が期待される。

機器，器具等の供与と使用状況は，新しく業務内容が定められ，また職員が各Section から集められてToxicology Sectionが一新されたため，業務内容に適した機器・器具等は乏しく，かなり厳しい状況にある。

供与された機器，器具等は各セクション間で共用されるべきものであり，またこの点を比側に何度も申し入れているが，他のSection の機器器具等の使用及び譲渡の実現は困難なようである。したがって，今後ある程度供与せざるを得ないものと考える。

3.5 研究部門（ RESEARCH SECTION ）

このSection は食品及び医薬品等の試験検査の支援部門として昭和63年８月に新設された。

職員は，Carmina Parce

Imelda Nobliza

Roswena Celis

Antonio Tuason　の４名である。

主な業務は，

① 各Section で行われるプロジェクト研究の調整を行う

② 試験検査を行うために，各種データを集め，評価する

③ 試験検査法を開発する

④ 研究所内の特殊な試験検査を指導する

である。

業務内容は，発足してからの期間が短いために，具体的な業務は少ないが，現在，アセトアミノフェン錠の品質試験法の開発と食品中のカビの分離と同定を行っており，今後の

Section の発展が期待される。

3.6　医薬品理化学分析部門

本調査団派遣までの化粧品を含む医薬品の理化学分析部門に関する技術協力は，年度毎の機材供与に加え，1987年５月～1988年11月の医薬品分析に関する長期専門家（柴崎利雄）の派遣及び予備的な技術指導及び調査を目的とした５回の短期専門家派遣であり，研修生の受入れは未だ実施されていない。

分析機器及び分析用機材は無償資金協力による主要測定機器の供与，1986，87年度の技術協力による測定機器及び消耗機材の供与により，通常の基本的な試験検査に必要最低限の機材はほぼ充足された状態である。なお，供与された機器類のほとんど稼働状態にあり，これまでの故障等への対応は，柴崎専門家の指導により，適切な措置がとられていました。機器類の維持管理については現在迄のところ大きな問題はなかったものの，柴崎専門家の離任後の対応については比側にゆだねられるところとなる。

技術移転は柴崎専門家による医薬品機器分析技術の移転が顕著な効果を上げ，液体クロマトグラフ，ガスクロマトグラフ，カールフィシャー水分定量装置，電気滴定装置，融点測定装置，デジタル施光計，薄層クロマトグラムスキャナー等の機器につき，少なくとも２名の職員がその取扱い法を取得した状態にあるとのことであった。これらの機器分析技術は日常業務にも利用されており，例えばこれまでの吸光度法によっていたアセトアミノフェンの定量を液体クロマトグラフ法に切り換え，試験の精度と試験能率の向上をはかっていた。このようにフィリピンが薬局方として用いている米国薬局方に繁用されている機器分析の多くがこれまでの技術移転により実施可能になった。

現在迄のところ，医薬品分析部門に関する技術協力は，柴崎専門家の多大な努力により，医薬品分析に繁用される機器による基礎的な分析技術の修得迄の段階は，暫定実施計画に沿い極めて順調に推移しており，フィリピン側の評価も高い。柴崎専門家は本年11月をもって任期を満了し帰国したので，これまでに修得した基礎技術の医薬品分析への応用は今後のフィリピン側の自助努力の課題といえる。

3.7　食品・医薬品監視・審査部門

食品及び医薬品の監視・審査に関するフィリピン国への技術協力は，食品については食品衛生法に基づき，医薬品について薬事法に基づき日本国内で実施している行政施策を基本として行われている。

昭和61年７月に署名された Record of Discussions（R/D）および Tentative Schedule of Implementation（T．S．I．）に基づき，食品及び医薬品の監視・審査部門に係るフィリピン国への日本側専門家の派遣は以上のとおりの実績がある。

(1) 食品の監視及び審査部門

1988年1月（2週間），6月（4週間）及び12月（2週間）に三回にわたり，それぞれ1名づつ食品監視及び輸入食品監視の専門家（厚生省生活衛生局食品保健課衛生専門官，厚生省神戸検疫所食品監視課監視係長及び厚生省成田空港検疫所食品監視課指導係長）を派遣した。

(2) 医薬品の監視及び審査部門では

1988年1月（2週間），6月（2週間）及び12月（2週間）に三回にわたり，それぞれ3名，2名，2名の医薬品の監視・審査の専門家｛（大阪府環境保健部薬務課長，大阪府和泉保健所衛生課長及び大阪府環境保健部薬務課主査），（大阪府環境保健部薬務課審査第二係長及び主査）並びに（大阪府狭山保健所衛生課長，大阪府環境保健部薬務課審査第二課主査）｝を派遣した。

4. 暫定実施計画の見直しと平成元年度協力実施計画

調査団と比側の協議により合意した暫定実施計画と平成元年度協力実施計画は，それぞれ表Ⅰ（19ページ）表Ⅱ（20ページ）のとおりであるが，以下，部門別に述べる。

4.1 動物飼育・管理部門

動物の繁殖・飼育は当初予定したよりも順調に進展しており，ＢＦＡＤ側の強い要請もあるので，動物実験の実施を早めることとした。また，動物飼育の成果そのものも，多角的な吟味（微生物学的，病理学的など）を経ていないので，その検査も実施したい。平成元年度に着手すべきこの部門の課題はおおよそ次のようである。

① マウス・ラットの繁殖・飼育状態の吟味：

a) 体重・外観の観察のほかに，血液学的検査，病理学的検査を加え，生育状態の評価を行う。血液化学的検査も必要であるが，次年度以降実施とする。

b) 微生物学統御の確認：ＳＰＦ状態の確認を行う必要がある。

c) 遺伝学的統御の考慮：コロニーが小さいので近交性が強まるおそれがある。交配方法の考慮が必要である。

② ウサギ繁殖・飼育の確立，実験用ウサギの供給の開始これには，現在コンベンショナルウサギを使用している実験室の清浄化などの対応も必要である。また，供給の当初には必要数を十分にまかなえない事態も予想されるので，切替えの手順を考慮する必要がある。

③ モルモット飼育・繁殖の開始

④ コンベンショナル動物を用いる動物実験の実施：

a) ネコを用いるヒスタミン試験

b) ウサギを用いる発熱性試験：これは漸次自家産動物と置換する（上述）。

⑤ マウス・ラットを用いる毒性試験の実施

a) 急性毒性試験

b) 連続投与（亜急性）毒性試験

⑥ その他の動物実験の実施

a) ウサギを用いる皮膚刺激性試験，および眼刺激性試験

b) ラットを用いる昇圧物質試験

このため，動物実験指導専門家を派遣する必要があるが，４月から３ヶ月の予定で毒性病理学専門家を派遣する予定とした。ＢＦＡＤ側カウンターパートの研修は２名ずつの要請があったが，受入れ枠の都合上１名づつとし，６月頃から６ヶ月間の研修を㈱食品薬品安全センター秦野研修所で行うよう計画した。

4. 2　衛生物部門

食中毒細菌の検査の技術移転は，本プロジェクトの当初計画には含まれていなかったものであるが，その必要性は大きく，ＢＦＡＤからの強い要請によって計画された。平成元年度には１名の研修生を受入れ，６ヶ月の訓練を行う計画とした。その研修の終了後，現地での実施を指導するため専門家の派遣も計画した。

4. 3　食品理化学分析部門

現在，同部門では食品の表示に伴う栄養成分を中心とした検査が，主な業務であるが，現業の業務量が多く，専門家による技術研修を受ける時間も制約を受けるほどである。しかしながら，後刻，技術研修の成果が業務遂行上反映されると思われるので，ＢＦＡＤ側に研修が十分に受けられるように，研修者に対して試験検査業務量の低減などの配慮を要望した。

試験検査技術の強化計画については，今後，食品衛生上の諸問題の多発も予想され，これらを解決する技術の修得と機器及び器具等の充実に計画の重点を移すことが必要である。

専門家の派遣については，技術の定着と機器器具の有効利用等のため長期専門家の派遣が望まれる。日本国内で広く，人材を求める必要がある。

平成元年度機材供与計画については，Toxicology Sectionと Reaserch Section の強化の面もあり，Food Sectionの機材の計画は，機器稼動のため付属品として不足しているもの他最低限，試験検査に必須なものを優先する事とした。

4. 4　毒性および研究部門

ＢＦＡＤでは，残留農薬試験と食品容器包装専門家の受け入れと研修生の派遣に対応して，これらの試験検査を行う職員を Toxicology Section に配置し，組織を整えている。

わが国への研修生の受け入れは，国立衛生試験所，食品添加物部で平成元年４月から容器包装に関する研修を行う予定になった。

前回までは，研修生の氏名，専門分野，経験年数等が来日まで判明しなかった為，計画が事前に立てられず，受け入れ側は準備不足となったが，来年度の計画は研修生 Toxicology Section の Miss Rosario Martinが予定され，研修に用いる対象物はフィリピンで用いられている容器包装を持参し，研修を行うことなどが決まり，期間中の研修が有効に活用され，フィリピンに適した技術移転が行われるものと期待される。

一方，技術の定着と機器器具等の有効利用等のため，Food Sectionと兼任の長期専門家の派遣が望まれる。

機材供与計画については，新しい Toxicology Section と Reseaech Section は，他の Section からの機器器具等の使用及び譲渡の実現は困難な状況にあり，業務内容に適した機器器具等の確保はかなり厳しい状況にある。これらのSection の強化及び日本での農薬およ

び容器包装の試験検査技術修得後，技術の定着のために，ある程度重点的に供与することを目的とした平成元年度供与機材（案）を作成した。

4.5　医薬品理化学分析部門

平成元年度については，従来の暫定実施計画どおり，つぎのような実施計画（案）で比側と合意した。

(1)　研修生受け入れについて：

①　昭和63年度分として医薬品機分析および標準品製造の技術移転を目的とする研修生1名を平成元年2月より6カ月の予定で国立衛生試験所大阪支所薬品部に受入れ，医薬品機器分析の応用技術及び標準品確立に関する基本的な概念の取得を図る。

②　平成元年度分として化粧品機器分析の技術移転を目的とする研修生を平成元年4月より6カ月の予定で国立衛生試験所環境衛生化学部に受入れ，機器分析の化粧品分析への応用技術の修得を図る。

(2)　専門家派遣について：

医薬品機器分析及び標準品製造の技術移転を目的として昭和63年度に受入れた研修生のフィリピンにおける後指導及び医薬品理化学分析に関する全般的指導を目的として平成2年1月頃より2ヵ月間短期専門家を派遣する。

(3)　機材供与について：

柴崎専門家の指導によりフィリピン側が作成した供与希望機材リストを点検整備し，医薬品分析及び化粧品分析に関する供与機材（案）リストを作成した。

4.6　食品・医薬品監視・審査部門

(1)　暫定実施計画の見直しについて

①　専門家の派遣

フィリピン側の意見，要望等を踏まえ暫定実施計画の変更の必要性について検討した結果，本計画は順調に進捗しており，更に，本計画全体の円滑な遂行を考慮した場合，暫定実施計画の変更を行う必要性はないものと思われる。

②　専門家の派遣期間

食品及び医薬品両部門ともに監視・審査の技術移転の実施方法について検討の余地はあるものの，その在り方の議論は後述する事とし，ここでは，専門家の派遣期間についてのみの報告とする。

昭和62年度及び昭和63年度の２年間で過去三回のフィリピン国へ専門家を派遣しているが，派遣期間についてのみを調査検討の結果，派遣期間が４週間であった食品監視・審査部門の一回（1988年六月）を除き，本プロジェクトの本来目的は両部門共に監視・審査の技術移転指導であるにもかかわらず，２週間の派遣期間のうち約１週間は現地の関係部局への挨拶まわり及び上席者との打ち合せ等に費やされ，実質の技術指導は５日間程度しか行われていない現状であった。

このような派遣専門家の技術指導の実質活動期間を考慮すると技術指導の在り方を改善する必要性とともに，現状の派遣期間では移転技術の内容も限定されると考えられる。

従って，２週間という現在の派遣期間での専門家派遣を今後も実施するとするならば，一回の専門家派遣でどの程度の技術指導を行うかを事前に十分検討する必要があると思慮する。

(2) 平成元年度協力実施計画について

派遣期間について多少議論の余地はあるにしてもフィリピンへの日本側専門家派遣に係る本年度の協力実施計画については暫定実施計画とおりの実施で比側と合意した。

実施済
計　画

表Ⅰ　フィリピン国食品医薬品検定センタープロジェクト暫定実施計画進捗状況（昭和63年12月現在）

		FY1986	FY1987	FY1988	FY1989	FY1990	FY1991
調査団派遣		実施協議	計画打合せ	巡回指導	（専門家チーム） （　　）	エバリュエーション	
研修員受入れ	動物飼育	87.3 実験動物飼育・管理				実験動物飼育・管理	
	動物実験		'87.10 生物検定		生物検定		
	微生物学		'87.10 無菌試験・真菌	抗生物質・非無菌製剤 88.11	食中毒細菌		
	食品分析		'87.5 食品添加物 '87.3 農　薬		容器包装 農　薬	食品添加物（天然） 食　中　毒	
	医薬品分析				化粧品分析 機器分析・標準品	安定性試験	
	監視・審査	食品〔集団〕 86.9	医薬品 '88.4	食品〔集団〕 '88.8 医薬品〔厚生省〕 (2)　医薬品 '88.7　'88.8	食品〔集団〕 医薬品〔厚生省〕	食品〔集団〕 医薬品〔厚生省〕	〔集団〕：JICA集団コース 〔厚生省〕：JICWELS薬事行政専門家研修
	その他		施設運営管理〔無償C/P〕 '88.4				
専門家派遣	チームリーダー	'87.4		'88.5			
	調査団	'87.4					
	動物飼育	機材計画 '86.11 飼料設計調査 '86.11	'87.10 動物管理	飼料製造　動物繁殖 '88.5 (2)　（マウス・ラット） 動物管理 '88.4	動物繁殖（ウサギ）	動物生産 動物繁殖　動物繁殖 ウサギ・モルモット繁殖	動物繁殖
	動物実験			生物検定・非性試験 '88.11	生物検定・非性試験	生物検定・非性試験	
	微生物学	機材計画 '86.11	リーダー カビ・電子顕微鏡 '87.9	抗生物質 '88.8 カビ・電子顕微鏡 '88.11	微生物	微生物	
	食品分析	機材計画 '86.11 施設・機器 '87.2	食品分析 '88.1 (2)	食品添加物 '88.7 農　薬 '88.10		容器包装 マイコトキシン	
	医薬品分析	機材計画 '86.11 施設・機器 '87.2	'87.5 医薬品理化学試験全般 生物薬剤学　医薬品分析 '87.8　'88.1	化粧品分析 '88.8	医薬品機器分析・標準品製造	化粧品分析	安定性試験
	監視・審査		食品監視・輸入品監視 '88.1 医薬品審査・医薬品監視 '88.1 (3)	食品監視・輸入品監視 '88.6 医薬品審査・医薬品監視 '88.6 (2)　(2)	食品監視・輸入品監視 医薬品審査・医薬品監視 (2)　(2)	食品監視・輸入品監視 医薬品審査・医薬品監視 (2)　(2)	
機材供与		50,000千円	60,000千円	60,000千円	（40,000千円）	：フィリピン側の要請に応じ、日本側予算の範囲内において必要：機材を供与する。	

表Ⅱ　フィリピン国食品医薬品検定センタープロジェクト平成元年度実施計画（案）

項　目	項　目　2	63年度前	4　5　6　7　8　9	10　11　12　1　2　3	平成元年度以降
専門家の派遣					
	リーダー	氏家 63/5/25 ←	2Y - - - - - - - -	- - - - - - - -	→ 02/5/24
	調整員	田坂 62/4/25 ←	3Y - - - - - - - -	- - - - - - - -	→ 02/4/24
	動物飼育管理	中曽 62/10/7 ←	- - - - - - - -	→ 01/10/6	
	〃　（動物生産）			1Y ⇔	⇔
	〃　（動物繁殖）	1/3/6 ←→ 3/18	2W ⇔		
	動物実験		3M ⇔ （西垣） （生物検定・毒性試験）		
	微生物			2M ⇔	
	医薬品機器分析・標準品製造			2M ⇔	
	監視審査（食品）		2W ⇔	2W ⇔	
	〃　（医薬品）		⇔	⇔	
	〃　（〃）		⇔	⇔	
調査団				⇔ ［専門家チーム］	
機材供与			実施協議	契約　　納品・送付	
各種事業					
カウンターパート	1. 動物実験（生物検定）		6M ⇔	⇔	
	2. 微生物学（食中毒細菌）		6M ⇔	⇔	
	3. 食品分析（容器包装）		6M ⇔		
	4. 医薬品分析（化粧品）		6M ⇔		
	監視・審査（食品）		* ［3M ⇔	⇔］	
	〃　（医薬品）		** ［1M ⇔］		
	5ケ年計画 有　・　無	国内委員会 開催日		○ リーダー会議	

*　ＪＩＣＡ集団研修コース

**　ＪＩＣＷＥＬＳ薬事行政専門家研修

5. プロジェクト実施体制

5.1 運営上の側面

(1) ＢＦＡＤの予算（表Ⅲ．ＢＦＡＤ予算総括表参照）

1988年度（1988年１月～12月）のＢＦＡＤの総予算額は16,625,000ペソ（１ペソ＝6.12円換算で 101,745千円）である。そのうち人件費は 9,931,000ペソ（60,778千円）が計上され全予算の60%を占める。また，事業実施に必要な運営費は，6,694ペソ(40,967千円）であり，40%である。この数字は，ＢＦＡＤの新施設が開所し，移転した1987年度に比べ，184%となっており，日常検査に使用する消耗品の購入さえ難しい時期があった移転当初の状況は飛躍的に改善されている。

1989年度予算案（1988年12月段階における保健省財務当局の予算案）では，人件費15,574,000ペソ（約95,313千円)(53%)，運営費13,800,000ペソ（約84,456千円)(47%)，計29,374,000ペソ（約179,769千円）となっており，全体で，前年比177%，1987年度に比較すると 326%と飛躍的に増加している。また，全予算に対する運営費の割合も年々増加しており，ＢＦＡＤ新施設に対する比側の並々ならぬ配慮がうかがわれる。この1989年度予算案が承認されれば，ＢＦＡＤ通常業務の運営管理はほとんど問題なく行われるとの事であった。

なお，この数字は，1987年12月の計画打合せ調査団来比時と若干のくい違いが見られるが，本表のほうが正確な数字との事である。

表Ⅲ．ＢＦＡＤ予算総括表

（単位：ペソ）

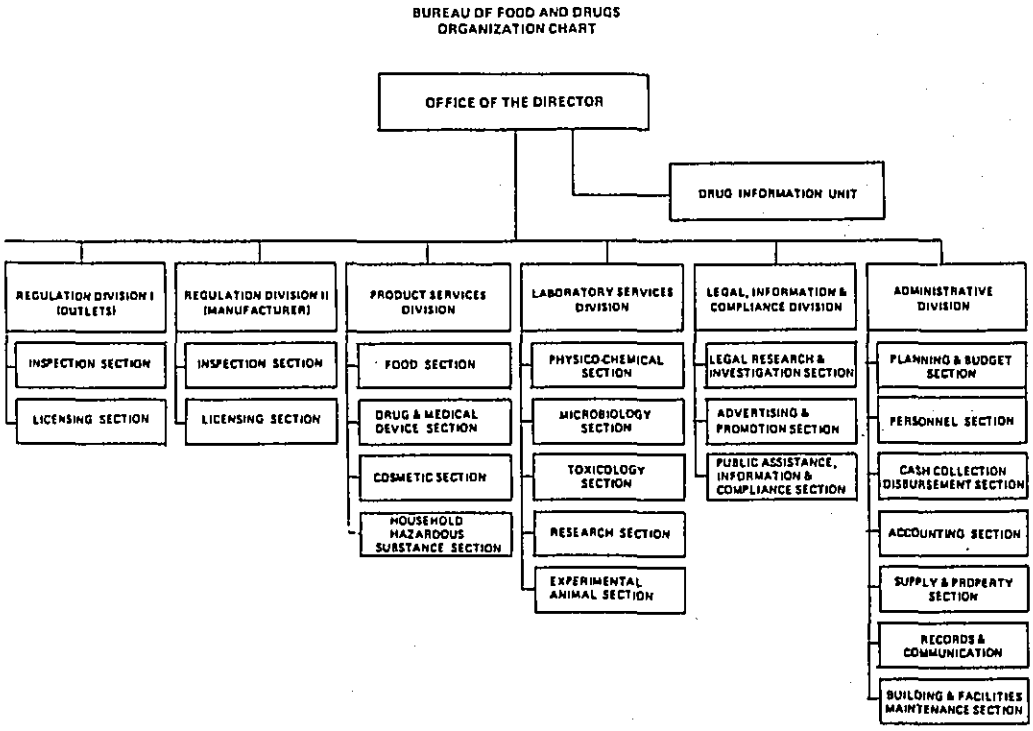
	1987年度（１月～12月）	1988年度	1989年度（案）
・給与，諸手当	4,510,000	7,503,000	11,592,000
・退職金，移転料他	1,337,000	2,428,000	3,982,000
人件費計	5,847,000（65%）	9,931,000(60%)	15,574,000(53%)
業務費	2,941,000	4,694,000	11,800,000
施設管理費	211,000	2,000,000	2,000,000
運営費計	3,152,000（35%）	6,694,000(40%)	13,800,000(47%)
総計	8,999,000	16,625,000	29,374,000

(2) ＢＦＡＤの組織

1988年６月に発行されたＢＦＡＤのパンフレットによるＢＦＡＤの組織図は表Ⅳのとおりであり，1987年保健省令（Executive Order №119)で定められたものとほぼ同一である。

ＢＦＡＤ局長の下に，６部１室が配置され，本プロジェクトと最も関係が深い検査部は，５課〔理化学（PHYSICP-CHEMCAL SECTION)，微生物学（MICROBIOLOGY SECTION)，毒性学（TOXICOLOGY SECTION)，研究・調査（RESEARCH SECTION)，実験動物舎（EXPERIMENTAL ANIMAL SECTION)〕から構成されている。職員数は事務職員および技術職員を合わせて235人であり，昨年の199人から36人増員されている。全スタッフの名簿は，表Ⅴに示した。

表Ⅳ．ＢＦＡＤ組織図



表V.　ＢＦＡＤスタッフ名簿

BFAD STAFF PERSONNEL

OFFICE OF THE DIRECTOR

Director

1. Susan Yanez
2. Imelda Mabalatan
3. Delfin Acebedo
4. Carmelita Cartel

Drug Information Unit

1. Elisa Caballero
2. Lourdes Cagaanan
3. Canonita Edmilao
4. Felicisima Silva

LEGAL INFORMATION & COMPLIANCE DIVISION

Investigation & Legal Research Section

1. Norma Villaresto
2. Iluminada Molina
3. Editha Paras

Public Assistance, Info, & Compliance Section

1. Nestorio Trinidad
2. Danilo Asuncion
3. Pablito Ferrer
4. Ronaldo Simbulan
5. Amando Silang Cruz

ADMINISTRATIVE DIVISION

Accounting Section

1. Norma Bayongan
2. Erlita Ma. Vergara
3. Isaias Iscala
4. Fausto Quizon, Jr.
5. Ma. Leoncia Melchor
6. Helen San Juan

Planning & Budget Section

1. Manuel Flores
2. Orlando Campos

Supply & Property Section.

1. Ma. Elena Francisco
2. Charito Manuel
3. Johnny Gutierrez

Personnel Section

1. Verena Benabese
2. Helen Grace Lagrisola
3. Demetria delos Santos
4. Elvira Mesina
5. Lydia Mendoza
6. Asuncion Bonaobra
7. Narciso Roca

Cash Collection & Disbursement Section

1. Ernesto Bernardo
2. Augusto Pascual
3. Cecilia Esguerra
4. Josephine Pacleb
5. Janet Volfango

Records & Communication Section

1. Teresita Maliwat
2. Reynaldo Joaquin
3. Rogelio David

Security/Driver

1. Benito Tapang
2. Norberto del Rosario
3. Rodolfo Constantino
4. Oscar Abalos

Building & Facilities Maintenance Section

1. Roberto Zara
2. Antonio Solicito
3. Edgardo Mongis
4. Buenaventura Solicito
5. Teodoro Trinidad
6. Mauricio Honrado
7. Emilio Aquino
8. Rizal Aguilar
9. Virgilio Mercado
10. Jose Oliver
11. Ulpiano Tanteo
12. Ruperto Cruz
13. Edwin Payad
14. Antonio Ledesma
15. Jonathan Romagos
16. Rogelio Rosalio, Jr.
17. Marcellno Benito
18. Honesto Mallorca

PRODUCT EVALUATION DIVISION

Drug Section

1. Nora Leongson
2. Luzviminda Marquez
3. Marivic Paulino
4. Grace Medina
5. Cecilia Cruz
6. Alicia Osias
7. Tomasa Gonzales
8. Emelita Romano
9. Ofelia Guion
10. Remedios Garcia
11. Ma. Angeles Jumawan
12. Analie Manipol
13. Lito Aguihap
14. Gemma dela Cruz
15. Rolando Angala

Food Section

1. Leonida Castillo
2. Leola Ibias

Cosmetics/Household Hazardous Products Section

1. Josefina Barahan
2. Olga Ringor

REGULATION DIVISION I

INSPECTION SECTION

1. Merced Uson
2. Evelyn Castolo
3. Estrellita Dulle
4. Dionisia Durante
5. Virginia Estrada
6. Julieta Garcia
7. Ma. Theresa Gutierrez
8. Necifora Iral
9. Norma Kabigting
10. Mary Ann Malicse
11. Baimona Mimbala
12. Antonieta Modanza
13. Misaela Neri
14. Virginia Perez
15. Zenaida Regodon
16. Ester Robles
17. Gloria dela Rosa
18. Hermelina Sevilla
19. Lucia Valencia

LICENSING SECTION

1. Rosita Caramancion
2. Minerva Reynaldo
3. Consolation Valete
4. Bernardita Dizon
5. Julita Fajardo
6. Lilian Alsaybar
7. Loreta Mirasol
8. Reinaldo Buan
9. Cecilio Pineda
10. Grace Zacarias

CUSTOM SECTION

1. Ador Abueg
2. Zenaida Bumanlag
3. Evelyn Fernandez
4. Conrado Ilagan
5. Gloria Peña
6. Ludivina Quitevis
7. Jesus Salamanca

REGULATION DIVISION II

INSPECTION SECTION

1. Rizalina Opinion
2. Josefina Gaspar
3. Aurora Bernal
4. Alicia Fernandez
5. Rufina Manansala
6. Marietta Bautista
7. Erlinda Francisco
8. Lilia Garcia
9. Albina Mendoza
10. Matilde Gener
11. Agapita Tuason
12. Anne Macam
13. Asuncion San Juan
14. Salvacion Jose
15. Edna Casimiro
16. Celia Esmeria
17. Wilhelmina Basa
18. Violeta Buen
19. Maritess Guevarra
20. Vilma Namoca
21. Theresa Guita
22. Frances Madura
23. Agnes Arellano

LICENSING SECTION

1. Ofelia Pesigan
2. Selya Baldonaza
3. Inocencio Cabanayan
4. Maricel Gaerlan
5. Aniceto Manayan, Jr.
6. Evangeline Sevilla
7. Radel Herras

LABORATORY SERVICES DIVISION

1. Naida de Ramos
2. Ma. Rowena Cura
3. Victoriano Alejar, Jr.

PHYSICO-CHEMICAL SECTION

DRUG:

1. Elisea Elvena

ANTIBIOTICS

1. Alicia Salazar

MICROBIOLOGY SECTION

1. Isabel Dy

2. Dory Duran
3. Jocelyn Alcasabas
4. Rosa Marcelina Cruz
5. Elenita Ong
6. Nazarita Lanuza
7. Zandra Bato
8. Edwin Villeza
9. Rosario Daria
10. Florlita Hernandez
11. Soledad Guzman
12. Socorro Abalos

2. Lydia Silvestre
3. Leonilo Agbay
4. Presentacion Hicban
5. Buenaflor Balasta
6. Teresita Vaño Uy
7. Teresita Romero
8. Zenaida Baumann
9. Leonora Advincula
10. Sylvia Villegas
11. Blanca Alfonso
12. Loida Isip
13. Anita Recilla
14. Delfin Sarmiento, Jr.

2. Emma Cabello
3. Evangeline Marinay
4. Clara Burbos
5. Almueda de la Cruz
6. Emily Malate
7. Teresita Franco

TOXICOLOGY:

1. Rosario Martin
2. Amelita Manalansan
3. Melinda Eusebio
4. Marilou Martinez
5. Amado Ong
6. Ederlina Claudio

FOOD

1. Josefa Lucero
2. Gloria Tomboc
3. Ma. Fely Senfelices
4. Rossana Peralta
5. Purificacion de Guzman
6. Elvira Nano
7. Thelma Rosario
8. Felicisima Alipio
9. Virginia Garcia
10. Catherine Cruz
11. Ma. Victoria Pabrua
12. Lourdes Cruz
13. Leny Macawile
14. Norman Henson

COSMETICS/HHS

1. Alicia Lorenzo
2. Remedios Pascual
3. Josefina Canafe
4. Lolita Villabroza
5. Editha Opulencia
6. Erwina Garcia
7. Eric Lima

RESEARCH SECTION

1. Carmina Parce
2. Antonio Tuazon

EXPERIMENTAL ANIMAL SECTION

1. Oscar Gutierrez, D.V. M.
2. Alexander Cortes, D.V.M.
3. Carlito Calderon, D.V.M.
4. Alvino Billones
5. Raul Cervantes
6. Antonio Martinez
7. Willy Mesina
8. Lito Pimentel
9. Ricardo Castro
10. Antonio Llanaresas
11. Antonio delos Reyes
12. Hermelando Santua
13. Noah Castolo
14. Artemio Padilla

5.2 実施上の問題点

今回，調査団と比側で協議された問題点は，3. 暫定実施計画の進捗状況および4. 暫定実施計画の見通しと平成元年度協力実施計画の項の中でも述べたが，その他，特に記載すべきと思われる点を以下に述べる。

(1) 医薬品理化学分析部門

① 日本人専門家による技術移転上の問題点：昨年度フィリピン側に善処を求めた，専門家の技術移転対象となるカウンターパートの明確化，技術移転への集中方促進等に改善は見られたものの，医薬品分析部門は日常業務が非常に多いためフィリピン側の技術移転への取り組みにも限度があり，効率的な技術移転の障害となっている。専門家による技術移転の効率化には，フィリピン側の適切な理解と対応が必要である。

② 供与機材の管理に関する問題点：これまでに多数の機器類，消耗機材が供与されたが，これら機材の保管管理態勢が充分整備されていない。例えば昨年度設置された薬品倉庫には保存薬品が無秩序に積み上げられた状態にあり，必要な薬品の取り出しは極めて困難な状態にあった。機器類の附属品，修理部品等についても保管管理態勢が不十分であり，専門家による技術指導や機材の有効利用の障害となっている。このような状態の改善のため，主要測定機器及び附属品類の保管管理態勢の整備，消耗機材の在庫管理の改善を申入れた。また測定機器類の共同利用態勢が十分でないとの専門家意見もあったので，機器共通利用の促進についても指導した。

③ 国家医薬品政策（National Drug Policy）の影響について：今回の調査によりフィリピンの国家医薬品政策の内容が明らかになった。この政策の実施には医薬品製剤についての国家的な生物学的同等性の保証が必須であり，それに必要な生物薬剤学的な技術の調整がＢＦＡＤに求められている。今後，国家医薬品政策の適正な実施に必須な生物薬剤学的技術の移転が本プロジェクトの医薬品理化学分析部門に要請されることも考えられるが，生物薬剤学は医薬品理化学分析の基本である分析化学とは全く基礎を異にする学問分野でもあるので，本プロジェクトの医薬品理化学分析部門に生物薬剤学的技術の移転を取り込むことについては今後比側と協議のうえ，慎重に応対する事が必要である。

(2) 食品・医薬品監視・審査部門

① 移転技術について

食品・医薬品の監視・審査部門における技術の移転，即ち行政施策の方法論の移転は，基本的にベーシックのところが同一であるということが相手国側に不快感を与えることなく無理なく受け入れられる最低必要条件である。

しかしながら，フィリピン国のように行政組織そのものがアメリカ的なところに加え

て法規制の方法についてもアメリカのそれを範としており，更に，基本的に日本と異なる国民性を有している国に対して，今後も食品分野にしろ医薬品分野にしろ日本の行政方策を加工せずにそのまま技術移転を実施しようとするならば，仮に現状の暫定実施計画の延長をしたとしても，その効果についてあまり期待できないものと思われる。

したがって，食品・医薬品の監視・審査部門に係る技術協力については，協力技術の内容について以下に列挙する項目を念頭に十分検念する必要がある。

ⓐ 食品における試験・検査と監視・指導あるいは医薬品における検定・検査と監視・審査の関連とその重要性

ⓑ 日本において過去に起きた事故等の例示を基にその対応と得られた教訓及び改善策（法律改正策）

ⓒ 効率的・効果的な監視，指導及び審査の方策（業態数の把握，機動力の確保，規格・基準の整備等）

ⓓ 事故の未然防止の手段としての情報収集の重要性

ⓔ 監視員の資質の向上（研修会などによる監視・審査技術の研さん）

ⓕ 営業者の資質及び意識の向上を図るための講習会の重要性（営業者責任の自覚の啓発，規制の必要性及び規制の必然性の理解等）

ⓖ 消費者の意識の向上（講習会の開催，広報紙の作成等）

以上の項目についてフィリピン国の現状を理解した上で現行行政体系の中で実施可能に加工しながら技術協力をする方策を検討することが重要である。

② 派遣専門家及び期間について

このような技術移転の方策を短期専門家派遣という位置づけで本プログラム遂行し技術協力の効果を期待するためには，

ⓐ その部門のエキスパートであること。（できうるならば複数のエキスパートによる同時平行的技術協力が望ましいこと。）

ⓑ 可能な限り長期間（３W～４W；実質活動期間２W以上）の派遣期間であることが望ましいこと。

③ 技術協力の変更について

以上のように日本，フィリピン両国間では基本的な点で異なるところから本プロジェクトでの効果的技術協力の難しさがある。

しかしながら，食品・医薬品の監視・審査部門についても，フィリピン側の食品・医薬品の監視・審査部門についても，フィリピン側の食品・医薬品の監視・審査のDevelopment of Systemのための技術協力につき両国間で合意されているところから，派遣専門家の削減あるいは廃止といった大幅な変更はプロジェクト全体に対するフィリピンサイドの不信感を抱かせる可能性も秘められているところから，専門家の派遣について

は継続実施することについて，その技術協力のactivityについてマイナーで，かつ効果的な技術協力方法を検討する必要がある。

6. 合同委員会の協議

6.1 協議の経緯と概要

比側との協議は1.3 日程記載の通り，１２月５日から８日まで，計５回にわたって行われ，その協議結果は，ミニッツに取りまとめられ，日比双方でサインが交わされた。協議内容の主要なものは以下のとおりである。

(1) 比側正式要請書提出等に係る事務手続きの迅速化について

比側からのプロジェクト方式技術協力に係る専門家派遣要請書（Ａ１フォーム），研修員受け入れ要請書（Ａ２，３フォーム），供与機材要請書（Ａ４フォーム）の提出に，これまで約２カ月を要しており，この点につき比側に手続きの迅速化を求めたところ，以前に比べ漸次改善してはいるものの，今後も迅速化に一層の努力をする旨回答を得た。

(2) プロジェクト運営管理上の側面について

① ＢＦＡＤのスタッフは，1987年度当初に比較してかなり増員されているものの，未だルーチン業務量と比して満足できる職員数とは言いにくく，適正な人員配置を比側に要請した。特に機器類のメインテナンスに関し，正規職員として電気技師の配置が必要な旨，申し入れ，比側は善処するとの回答であった。

② ＢＦＡＤ予算については，現状ではかなり満足できる額であり，特にミニッツに記載する必要もないとの議論もあったが，実験動物舎で，休日も出勤して，動物の世話をしている人員に対する手当が支払われてない事実があり，この点につき比側に善処方求める意味でも，ミニッツに記載した。比側は，今後はこの手当を支払うと約束した。

③ 日本側から供与された機材・試薬の管理台張と呼べるものがない為，管理の為に人員を配置して，管理台張を作成するよう比側に要請し，比側はこれについても善処する旨約束した。

(3) 比側の要請事項

比側より1990年度の実施をめどに以下の事柄について日本側で検討あるよう要望があった。

① 医薬品審査，特に医薬品の副作用に関する，比側カウンターパートの日本での技術研修

② 実験動物舎の為の倉庫建設

調査団は，日本に持ち帰り関係機関と協議・検討する旨回答した。

(4) 比側の緊急要望事項

比側から，実験動物舎に関し，①ヘパフィルターシステム，②排気用ファンの設置に関し，至急対応してほしいとの要望があったが，その必要性・緊急性について日本側から再考を要する意見も出た。調査団としては，一応ミニッツには記載するものの，比側にて再検討のうえ，必要度・緊急度を再検討のうえ正式な要請書が提出されれば，対応を検討する旨回答した。

(5) 現有施設の拡張工事および水供給・処理システムの改善について

比側より，現有施設が近い将来手狭になる事が予想され，その拡張工事とともに，現在の水供給・処理システムについても改善工事の要求があった。しかしながら，現状でも技術協上実施上支障がないことおよびプロジェクト方式技術協力の枠内では対応が困難である旨，比側に説明した。

(6) そ の 他

ミニッツには記載しなかったが以下の事柄について日比双方で合意された。

① 平成元年度供与機材について

平成元年度の供与機材については，比側の要望する機材リストの提出がなされ，調査団員が各担当部門について，比側と協議し再確認した。このリストを調査団が日本に持ち帰り，参考見積りをとって価格を調査のうえ比側に連絡し，平成元年度予算額が決定した時点で，優先度を考慮した最終機材リストを比側からＡ４フォームとして提出する事となった。

② 昨年１２月計画打合せ調査団との協議の中でミニッツに記載された比側要望事項については，比側要望に添って大部分が実施されたが，実施されなかった事項はその必要性がプロジェクト運営上，特に認められなかったものであり，現状で特に支障はない。しかしながら，検体の輸送と検査要員の交通手段としての車輌の供与については，比側より再検討の強い要望があった。日本側としては，「現状で特に業務上支障は認められず，早急に供与する必要はないと判断している上，本来であれば，比側予算にて購入すべきものである」旨の回答をした。

MINUTES OF THE DISCUSSIONS BETWEEN THE JAPANESE ADVISORY SURVEY TEAM AND THE AUTHORITIES CONCERNED OF THE GOVERNMENT OF THE REPUBLIC OF THE PHILIPPINES ON THE JAPANESE TECHNICAL COOPERATION FOR THE FOOD AND DRUGS LABORATORIES PROJECT

The Japanese Advisory Survey Team (hereinafter referred to as "the Team") organized by the Japan International Cooperation Agency, headed by Dr. Hiroshi Ono visited the Republic of the Philippines from December 1 to 9, 1988, for the purpose of reviewing the activities concerning the Food and Drugs Laboratories Project (hereinafter referred to as "the Project").

During its stay in the Republic of the Philippines, the Team observed the over-all progress and exchanged views and had a series of discussions with the Philippine authorities concerned about evaluation and a further implementation of the Project.

As a result of the discussions, both sides confirmed the items which are described in the attachment.

Manila, December 8 , 1988

Dr. Hiroshi Ono Leader, Advisory Survey Team, Japan International Cooperation Agency(JICA), JAPAN	Mrs. Catalina C. Sanchez Director, Bureau of Food and Drugs, Department of Health, The Republic of the Philippines

ATTACHMENT

1. The cooperation programme under the Project from FY1986 to FY1988 has been carried out as is shown in Annex I.

2. The Tentative Schedule of Implementation modified on December 18, 1987 is remodified as is shown in Annex II.

3. The cooperation activities in FY1989 shall be carried out in line with the Annual Work Plan as is shown in Annex III.

4. In order to carry out the Project more smoothly and fruitfully, both sides shall continue to make their best efforts concerning the matters mentioned below.

4.1 The Japanese side stated to the Philippine side that the normal procedure under the Colombo Plan Technical Cooperation Scheme (A-1, A-2,3 and A-4 form) should be taken more smoothly by the Philippine side for more effective project activities. The Philippine side agreed to the comment of the Japanese side and presented that they would make betterment of such procedure.

4.2 For the progress of effective technical cooperation, the Japanese side recommended that the measures to be taken by the Philippine side are as follows:

(1) to appoint the appropriate number of staff in each division and assign permanent electrical and electronic engineers for the effective maintenance of the facilities and equipment.

(2) to secure enough budget including the payment of overtime work for the technicians working at the animal house.

(3) to assign personnel in charge of proper care and maintenance of the equipment,parts and accessories.

4.3 The Philippine side submitted the draft proposal to the Japanese side in connection with the content of technical cooperation for the Japanese Fiscal Year 1990: as indicated hereunder:

(1) Counter-part training on Evaluation of Drugs specifically on adverse drug reaction.

(2) Provision for additional storage facilities specifically for the use of the experimental animal house.

The Japanese side mentioned that the proposal would be studied by the concerned institutions in Japan for possible implementation.

4.4 The Philippine side requested the Japanese side the urgent provision and installation of the following for the use of the experimental animal house.

(1) HEPA filter system

(2) Exhaust fans

5. The Philippine side requested the Japanese side for the assistance in the improvement of water supply system and extension of the building.

The Japanese side mentioned that these proposals should be studied in detail by the Philippine side and submit the complete proposal to the Japanese side for further consideration.

ANNEX I .COOPERATION ACTIVITIES FROM FY1986 TO FY1988

Note: * provisional

1. ANIMAL CARE AND CONTROL

ⓐdispatch of Japanese experts

Dr. Hiroshi Ono	cooperation planning (equipment)	1986.11. 4 - 11. 8
Dr. Tsuneo Otaki	feed materials	1986.11. 4 - 11.12
Mr. Yoshiki Taguchi	〃	1986.11. 4 - 11.17
Mr. Hisashi Fushiya	〃	〃
Mr. Masatsugu Nakaso	animal control	1987.10. 7 - 1989.10. 6
Dr. Minoru Izutsu	animal control	1988. 4.21 - 5.14
Mr. Susumu Kusaka	feed preparation	1988. 5.27 - 6.10
Mr. Hiroshi Usui	〃	〃
*(not yet definite)	animal breeding	2 weeks in Feb.,1989

ⓑPhilippine counterpart training in Japan

Mr. Oscar G. Gutierrez	animal care and control	1987. 3.29 - 9.28
Mr. Albino B. Billones	〃	〃

2. TOXICOLOGICAL EXAMINATION AND BIOASSAY

ⓐdispatch of Japanese experts

Dr. Nobuyuki Ogawa	bioassay	1988.11.28 - 12.10

ⓑPhilippine counterpart training in Japan

Ms. Dory Duran	bioassay	1987.10.13 - 1988. 3.29

3. MICROBIOLOGY

ⓐdispatch of Japanese experts

Dr. Shigeo Iwahara	cooperation planning (equipment)	1986.11. 4 - 11.12
〃	microbiology in general <Team Leader>	1987. 4.18 - 9.17
Dr. Atsuo Ujiie	microbiology in general <Team Leader>	1988. 5.25 - 1990. 5.24
Dr. Kosuke Takatori	mycology and electron microscopy	1987. 9.21 - 10. 9
〃	〃	1988.11.28 - 12.10
Dr. Satoshi Mizuno	antibiotics	1988. 8. 3 - 8.17

ⓑPhilippine counterpart training in Japan

Ms. Carmina J. Parce	mycology and electron microscope	1987.10.13 - 3.29
Ms. Zenaida T.Baumann	antibiotics	1988.11.29 - 1989. 7. 4

4. PHYSICOCHEMICAL ANALYSIS OF FOOD

ⓐdispatch of Japanese experts

Dr. Yukio Saito	cooperation planning (equipment)	1986.11. 4 - 11.12
Dr. Takashi Suzuki	cooperation planning	1987. 2.24 - 3. 5
〃	pesticides	1988.10.14 - 12.13
*(〃)	〃	1989. 1.10 - 2. 9
Dr. Takashi Yamada	food additives	1988. 1.27 - 2.10
Dr. Tadashi Shibata	〃	〃
〃	〃	1988. 7. 7 - 10. 6

ⓑPhilippine counterpart training in Japan

Ms. Ofelia M. Alba	pesticides	1987. 3.29 - 9.28
Ms. Alicia T. Lorenzo	food additives	1987. 5. 5 - 9.28
*(Ms. Amelita P. Manalansan)	pesticides	6 months from Mar.,1989

5. PHYSICOCHEMICAL ANALYSIS OF DRUGS

ⓐdispatch of Japanese experts

Dr. Yasushi Takeda	cooperation planning (equipment)	1986.11. 4 - 11.12
Dr. Toshio Shibazaki	cooperation planning	1987. 2.24 - 3. 5
〃	physicochemical test (general)	1987. 5.17 - 1988.11.16
Dr. Hiroshi Ogata	biopharmacy	1987. 8. 8 - 8.14
Dr. Satoshi Okada	instrumental analysis & reference standards	1988. 1.27 - 2.10

ⓑPhilippine counterpart training in Japan

*(Ms. Nazarita T. Lanuza)	instrumental analysis of drugs and preparation of reference standards	1989. 2. 6 - 8.15

* provisional

6. INSPECTION AND EVALUATION

ⓐdispatch of Japanese experts

Dr. Shuji Ota	cooperation planning(food)	1988. 1.27 - 2.10
Dr. Ikuo Tsukamoto	inspection of import & export of food	1988. 6.29 - 7.26
Dr. Satoru Sakai	〃	〃
Mr. Susumu Doi	cooperation planning(drugs)	1988. 1.12 - 1.20
Mr. Katsu Kobayashi	〃	〃
Mr. Hirotaka Mashimo	〃	〃
Mr. Takeshi Kotani	inspection and evaluation of drugs	1988. 6.29 - 7.13
Mr. Kiichiro Shiraishi	〃	〃
Mr. Shigeyoshi Yunoki	〃	1988.11.29 - 12.13
Mr. Takeo Yamamoto	〃	〃

ⓑPhilippine counterpart training in Japan

Ms. Estrellita A.Dulle	inspection of import & export of food	1988. 3.22 - 4.21
Ms. Lucia S. Valencia	inspection & evaluation of drugs	1988. 8. 8 - 9. 7
.....	.....	.....
Ms. Gloria W. Pena	inspection of import export of food (JICA group training course)	1986. 9.16 - 12. 9
Ms. Lilia E. Garcia	〃	1986. 8.29 - 12. 8
Ms. Eusebia Regodon	Pharmaceutical affairs (JICWELS study programme)	1988. 7. 4 - 8. 6
Ms. Lucia S. Valencia	〃	〃

7. OTHER FIELDS

ⓐdispatch of Japanese experts

Dr. Shigeo Iwahara	team leader	1987. 4.18 - 10.17
Dr. Atsuo Ujiie	〃	1988. 5.25 - 1990. 5.24
Mr. Atsushi Tasaka	coordinator	1987. 4.25 - 1990. 4.24

ⓑPhilippine counterpart training in Japan

Mr. Rodrigo A.Castillo	plant operation	1988. 3.22 - 6.25

* provisional

ANNEX II TENTATIVE SCHEDULE OF IMPLEMENTATION OF THE FOOD AND DRUGS LABORATORIES PROJECT
(as of December, 1988)

	FY1986	FY1987	FY1988	FY1989	FY1990	FY1991
Survey team	Implementation	Planning consultation	Advisory survey team	(Expert team)	Evaluation	
C/P Training in Japan (a)		'87.3 Animal care & control			Animal care & control	
(b)		'87.10 Biological assay		Biological assay		
(c)		Sterility test, Mycology '87.10		Antibiotics '88.11 Food poisoning bacteria		
(d)	'87.3	'87.5 Food additives Pesticides		Food container & wrapping Pesticides	Food additives (natural) Natural toxicant	
(e)			Instrumental analysis & Preparation of reference standard	Cosmetic analysis	Stability test	
(f)	Food inspection * '86.9	Drug administration '88.4	Food inspection * '88.8 Drug administration * (2) '88.7 '88.8	Food inspection * Drug administration *	Food inspection * Drug administration *	* : Group Training Course by JICA * : Pharmaceutical Affairs
(g)		Plant operation '88.4				
Japanese Expert team Leader	'87.4	'88.5				
Coordinator	'87.4					
(a)	Planning '86.11 Planning '86.11	Animal control '87.10 Feed preparation '88.5 (2) Animal control '88.4 Breeding(mouse, rat)		Animal production Breeding(rabbit)	Animal Breeding Breeding(rabbit, guinea pig)	Animal Breeding
(b)			Bioassay, toxicological test '88.11	Toxicological test, Bioassay	Toxicological test, Bioassay	
(c)	Planning '86.11	Leader ( ) Mycology, Electron microscope 87.9	Antibiotics '88.8 Mycology, Electron microscope '88.11	Microbiology	Microbiology	
(d)	Planning '86.11 '87.2	Food additives '88.7 Food analysis '88.1 (2)	Pesticides '88.10	Food container & wrapping	Mycotoxin	
(e)	Planning '86.11 '87.2	'87.5 Physicochemical test in general Biopharmacy, Drugs analysis '87.8 '88.1		Instrumental analysis & Preparation of reference standards	Cosmetic analysis	Stability test
(f)	(FOOD) (DRUGS)	Inspection of import & export, specifications & standards '88.1 '88.6 '88.11 Inspection '88.1 (3) '88.6 (2) '88.11 (2)		Inspection and evaluation (2) (2)	(2) (2)	
Equipment	Necessary equipment will be provided within the budget allocation of the Government of Japan in response to the application from the Government of the Republic of the Philippines					

※ (a) Care & breeding of experimental animals (b) Bioassay and Toxicological Test (c) Microbiological examination (d) Physicochemical analysis of food
(e) Physicochemical analysis of drugs (f) Development of systems in the inspection and evaluation of food & drugs (g) Others

※ 'Drugs' can include cosmetics

ANNEX III

ANNUAL WORK PLAN
FOR
THE FOOD AND DRUGS LABORATORIES PROJECT

Fiscal year 1989

I. Counterpart Training in Japan

Biological assay ---------- 1 person (6 months from June, 1989)
Food poisoning bacteria ---------- 1 person (6 months from August, 1989)
Food container & wrapping ---------- 1 person (6 months from April, 1989)
Cosmetic analysis ---------- 1 person (6 months from April, 1989)
[Drug administration ---------- 1 person (1 month)]
[Food inspection ---------- 1 person (3 months from September, 1989)]

II. Japanese Expert

(Team Leader ---------- 1 person (2 years from May, 1988))
(Coordinator ---------- 1 person (3 years from April, 1987))
(Animal control ---------- 1 person (2 years from October, 1987))
Animal production ---------- 1 person (1 year from October, 1989)
Breeding (rabbit) ---------- 1 person (2 weeks in July, 1989)
Bioassay & Toxicological test ------- 1 person (3 months from April, 1989)
Microbiology ---------- 1 person (2 months from January, 1990)
Instrumental analysis of drugs and preparation of reference standard
---------- 1 person (2 months from January, 1990)
Inspection and evaluation of food --- 2 persons (one for 2 weeks in June, 1989 & the other for 2 weeks in November, 1989)
Inspection and evaluation of drugs -- 4 persons (two for 2 weeks in June, 1989 & the others for 2 weeks in November, 1988)

III. Provision of equipment

Necessary equipment will be provided by JICA for the Project within the range of Japanese budget.

資　　料

The National Drug Policy

INTRODUCTION

The formulation of a National Drug Policy was the product of a long process of consultations and deliberations that arose as a response to a felt need which was conveyed to the government by people from various sectors of society.

In fact, in all the President's regional consultations, the problem of drugs and medicine being beyond the reach of the majority of Filipinos was among the most common issues raised. Similar consultations by the DOH yielded the same complaint and citizens pressed for some form of government intervention and relief. There was widespread concern over the issues of availability of drugs and medicines, which could not be ignored. At the same time, there was a basic agreement that free market forces could not resolve these problems.

The DOH recognizes the fact that drugs and medicines are a vital component of health care. Given the low levels of income of the vast majority of the Philippine population, the cost of pharmaceuticals is a major, if not dominant, factor in the overall cost of health care. Furthermore, the Constitution recognizes the citizens' right to health and mandates the government to address the issue of assuring the availability of necessary drugs and medicines.

Aware of these concerns, the Department of Health initiated and supervised a process of policy formulation with four basic components: a) determination of the need, scope, and process for policy formulation, 2) conduct of orderly and documented consultations, 3) conduct of local research, and 4) conduct of international research. Initial studies conducted from September to October 1986 arrived at a consensus to develop the Policy.

Subsequently, the DOH conducted consultations from November 1986 to March 1987 among the different sectors of the drug industry, the medical profession, and consumer groups. These included two major multisectoral conferences with 61 organizations represented and 99 individual participants. During these fora, 25 position papers were submitted, resulting in the identification of seven issues: 1) a proposed Essential Drug List (EDL), 2) the use of Generics versus brand names, 3) advertising and promotions, 4) procurement and self-sufficiency, 5) self-medication, 6) basis for registration of pharmaceuticals, and 7) pricing.

Simultaneously with these discussions, both local and international research activities were conducted. The local research component was carried out between September 1986 and March 1987. A situational analysis and seven working papers on the issues mentioned previously were prepared. A bibliography of local research efforts and papers dealing with drugs and pharmaceuticals was also prepared. The international research component, conducted between November 1986 to April 1987, focused on the compilation of the national drug policies of ten (10) countries, extensive consultations with the World Health Organization, face-to-face discussions with experts in Indonesia, Thailand and Malaysia, and inquiries with local embassies of ten (10) countries.

On April 30, 1987, during the inauguration of the Bureau of Food and Drug Laboratories in Alabang, Muntinglupa, President Corazon C. Aquino announced the National Drug Policy and the government's commitment to its implementation.

The National Drug Policy, Its Four Pillars or Components

The National Drug Policy is set on four main pillars designed to eventually bring about the availability and affordability of safe, effective, and good-quality drugs for all sectors of the country, especially for the poor who need them most, but who can least afford them. These four pillars form an integral unit, mutually complementary and supportive of each other.

The first pillar is the *assurance of the safety, effectiveness and usefulness of pharmaceutical products through quality control.* This will involve the regulation of the importation, manufacture, marketing, and consumer utilization of all drugs and their intermediates.

The absence of effective and sound regulation of the drug industry allowed the importation and sale of drugs whose efficacy have not been scientifically established or confirmed, and the continued sale of drugs which are banned or considered unsafe in other countries for reasons of safety. To remedy this unfavorable state of affairs, the capabilities and powers of the Bureau of Food and Drug are being strengthened and expanded, as it will be the lead agency in the regulation of the industry. The inauguration of its new laboratories in April 1987 marked the first step in this direction. A strengthened BFAD will be able to function as the national quality control center and regulatory body for the pharmaceutical industry in the Philippines.

The second pillar rests on the *promotion of the rational use of drugs by both health professionals and the general public.* Rational use of drugs refers to a carefully-considered pattern of behaviour on the part of the consumer – be he the prescribing physician or the end-user. This will limit the use of medicines, be they commercial preparations or herbal medicines, to situations where there are clear indications for them. Furthermore, only the most necessary and scientifically-proven efficacious drugs should be used.

Bound up in this activity is the creation of a National Drug Formulary (NDF) which shall list those drugs which are most essential for therapeutic usage. Aside from this, the rules and regulations governing the promotion and advertising of pharmaceutical products shall be reviewed and amended in order to contribute towards the promotion of rational use of drugs. With these twin moves, consumers will now be properly guided as to which drugs to use for their particular needs and conditions.

The third pillar of the National Drug Policy is the development of *self-sufficiency in the local pharmaceutical industry.* This pillar seeks to strengthen Filipino capabilities in government as well as the private sector for the manufacture of basic and intermediate ingredients for drugs and medicines. By developing a capability to produce essential drugs locally, the country's dependence on multinational drug firms can be greatly reduced.

This pillar is an ambitious undertaking towards which trade and investment policies must be supportive. More and more, the government will encourage the strengthening of local capabilities in government as well as the private sector for the manufacture of basic and intermediate ingredients for drugs and medicine. With increased self-sufficiency, local industry will be in a better position to respond to the needs of the population for the most essential of drugs.

The fourth pillar of the National Drug Policy relates to the *targeted procurement of drugs by government* with the objective of making available to its own clientele, basically government-owned and operated hospitals and health centers which cater to the lower-income sectors of the society, the best drugs at the lowest possible cost. It is widely acknowledged that the government is the single largest purchaser of drugs in the country, allocating half of its health budget for drugs and medicines.

The government, therefore, is in a strong position to influence the market, providing initiative and direction so that the benefits will extend to all the sectors of the society. Bulk purchasing and contract manufacturing are among the mechanisms by which the government can exert its influence. Through these mechanisms, the government can guarantee that only high-quality drugs are used in its hospitals and health centers.

The four pillars of the National Drug Policy form a dynamic whole and each element is meant to reinforce the other three. The tenets of rational use will serve as a basis for regulation in both government and private sectors. In turn, fair and thorough regulation should fuel the incentives for rational use. The active participation of government in procurement, production, and distribution will lead the way towards some measure of self-sufficiency. This should also provide impetus for private enter-

prise to move toward the manufacture of the more basic ingredients of drugs, if private industry is to retain its competitive edge.

Our hope is that this National Drug Policy will eventually remedy the gross imbalance in the Philippine pharmaceutical market where a strong supply side, which is controlled by multinational corporations and almost completely import-dependent, dominates an extremely weak demand side, which is a poorly informed public that is dependent on health professionals who are invariably influenced by the aggressive and expensive marketing practices of pharmaceutical companies. It is, of course, anticipated that such a program will be opposed by elements who are reaping enormous profits from the maintenance of the industry *status quo*. Already, such resistance has manifested itself in a lobby against the National Drug Policy and in letters of concern from two U.S. senators and the President of the American Chamber of Commerce in the Philippines.

The Department of Health seeks your support and the support of all sectors of society in the effort to implement the National Drug Policy. The NDP relates to the health of each and every Filipino and certainly deserves the cooperation of everyone.

Primer on the National Drug Policy

1. What is the objective of the National Drug Policy?

The National Drug Policy (NDP) is a policy and program of the national government to ensure that safe and effective drugs are made available to all Filipinos at any time and place and at a reasonable and affordable cost.

2. When was the National Drug Policy announced?

President Corazon C. Aquino enunciated the National Drug Policy on 30 April 1987 during the inauguration of the new Bureau of the Food and Drugs (BFAD) building in Alabang, Metro Manila.

3. Why is the NDP needed?

The unavailability and unaffordability of safe and effective drugs has always been a problem in this country. Ironically, the local market is flooded with 12,000 different drugs. Many of these are of dubious quality; most of them are beyond the means of most consumers. And yet, according to the World Health Organization, 90% of all ailments can be cured by 250 drugs which may be deemed to be essential. There is a need to put order into a chaotic situation and to promote the rational use of drugs.

4. How was the NDP formulated?

Through the initiatives of the Department of Health, a Task Force on Pharmaceuticals was set up in June 1986. The Task Force went through several steps in formulating the NDP.

a) *Consultations.* Two major multi-sectoral conferences were held with 61 organizations and 99 individual participants in attendance. Consultations were also conducted with the pharmaceutical industry, professional organizations, academic and consumer groups. During these fora, 25 position papers were submitted to the Task Force.

b) *Local Research.* The local research component was carried out between September 1986 and March 1987. A review of local research efforts and publications dealing with drugs and pharmaceuticals was undertaken. A situational analysis that identified seven basic issues in the pharmaceutical industry was developed by the Task Force.

c) *International Research.* The international research component was conducted between November 1986 and April 1987 with visits Indonesia, Malaysia, and Thailand. During that period, extensive face-to-face consultations were held and the experiences of other countries in formulating a drug policy were compiled and analyzed.

5. What are the components of the NDP?

The NDP rests on four pillars which form an integral unit and are mutually complementary and supportive of each other. These are:

a) *Quality Assurance of Drugs* – The quality assurance of safe and effective pharmaceutical products through quality control is a basic need. This pillar requires the regulation of the importation, manufacture, marketing, and consumer utilization of all pharmaceutical products. This is the task of the BFAD.

b) *Rational Use of Drugs by Health Professionals and Consumers* – The second pillar calls for the promotion of the rational use of drugs by health professionals and consumers. Rational use of drugs refers to the practice of

using only the necessary and effective drugs in treating an illness. Abuse and misuse of drugs are the antitheses of rational use.

c) *National Self-Sufficiency in Pharmaceuticals* – The third pillar of the NDP is the development of national self-sufficiency in drug manufacturing. It is intended to reduce the country's dependence on the multinational drug companies.

d) *Rationalization of the DOH's Procurement Program* – Since the national government is the single biggest buyer and user of pharmaceutical products, its procurement program can be designed to achieve economies of bulk purchasing and enhance the impact of DOH resources.

6. How will the objectives of the NDP be achieved?

a) To assure the quality of drugs and medicines, the DOH is strengthening the capabilities of BFAD to undertake quality control, product registration, and licensing of sales establishments. Current efforts are underway at the BFAD to delist medicines that are banned, restricted or withdrawn from other countries but are still available here.

b) To ensure the rational use of drugs by consumers and health professionals, the following are underway:

1) the passage of bills in Congress requiring generic labelling, prescribing, and dispensing of medicines;
2) the creation of the National Drug Formulary by the National Drug Committee (see question 8);
3) the regulation of the advertising and promotion of pharmaceutical products.

c) To achieve self-sufficiency in basic manufacturing, a fundamental plan is being developed with the participation of the United Nations Industrial Development Organization (UNIDO). Based on this plan, private investment will be given incentives to produce raw materials and intermediates of pharmaceutical products.

d) To rationalize DOH procurement of medicines, purchases have been based on generic nomenclature. All future purchases will be based on the National Drug Formulary.

7. What are generic names? What are the advantages of using them?

A generic name is a simpler term for the scientifically-recognized active ingredient of a drug. For example, paracetamol is the generic name for n-acetyl-p-aminophenol. Paracetamol is a medicine to control fever. Brand names of paracetamols include Tempra, Biogesic, and Tylenol.

Using generic names will reduce the cost of treatment by reducing the promotions and advertising costs which are associated with brand-name drugs.

Some examples of generic names, brand names, and their prices are:

Therapeutic use	Generic name		Brand name	
For fever	Paracetamol	P0.50	Biogesic	P0.62
			Tempra	P0.70
			Tylenol	P1.00
Antibiotic	Ampicillin (250 mg.)	P2.02	Pensyn	P2.99
			Pembritin	P3.35
			Amopen	P3.47
Vitaminc C	Ascorbic Acid	P0.35	Citrovit	P0.67
			Cetrin	P0.68
			Cecon	P1.20

8. What is the National Drug Formulary (NDF)?

The NDF is the list of medicines officially recognized and approved by the DOH. It is composed of a core list of medicines considered essential and a complementary list of drugs considered useful if not essential. This formulary is currently being prepared by the National Drug Committee and when completed will be regularly revised and updated.

9. What is an Essential Drugs List (EDL)?

The EDL is a concept promoted by the World Health Organization and refers to those drugs which cure the vast majority of illnesses and should be affordable and available to all persons. The EDL will be incorporated into the National Drug Formulary.

10. What are the obstacles to the successful implementation of the NDP?

The obstacles include:

a) companies that stand to lose money when their products which are judged unsafe and ineffective are delisted and taken off the market. As is already happening, these companies file court suits to prevent the delisting of their products.

b) fly-by-night companies which will try to take advantage of the new law on generic labelling, prescribing, and dispensing to market products of inferior quality with the hope of getting away with it.

c) individuals and groups that want to maintain the *status quo* because they benefit from it in terms of large revenues or promotional perks.

11. How can medical practitioners promote the NDP?

Physicians should practice generic prescribing. They should also maintain a healthy professional distance from the drug companies. Medical societies should provide better postgraduate education to their members so that reliance on drug companies for updating through drug promotions is minimized.

12. How can pharmacies and sales establishments promote the NDP?

Pharmacies and sales outlets should provide information concerning generic names of brand-name drugs and their comparative prices. This service will afford the consumer a wider and more informed choice of medicines for his/her needs.

13. How can the ordinary citizen promote the NDP?

The ordinary citizen must use medicine wisely. He must seek pertinent information from his physician and from the pharmacist on medicine that is necessary and affordable to him/her. He must inform himself about the range of choices in a generic prescription in order to make the proper purchase.

14. Who manages the implementation of the NDP?

The NDP Management Committee is a special group within the DOH which oversees the implementation of the NDP. It is headed by the Assistant Secretary for Standards and Regulations.

The group has several units.

a) the Advisory Committee to BFAD is responsible for spearheading the upgrading of capabilities within BFAD. Experts from the UP College of Pharmacy and the Department of Pharmacology of the UP College of Medicine are members of this committee.

b) the National Drug Committee (NDC) is a team of pharmacologists, pharmacists, and clinicians whose main task is to prepare the National Drug Formulary and recommend to the BFAD the drugs for delisting.

c) other units involved in administration, legal affairs, and communications and information.

For further inquiries, please call or write:

1. Office of the Secretary of Health, DOH
   Ask for the Public Relations Officer
   Telephone: 711-61-05
2. Public Information and Health
   Education Service, DOH
   Ask for National Drug Policy
   Information Officer
   Telephone: 711-63-05
3. Bureau of Food and Drugs
   DOH, Alabang
   Ask for National Drug Policy Coordinator
   Telephone: 842-22-13

The Westly-Bengzon Letters

May 31, 1988

Dr. Alfredo R.A. Bengzon
Secretary
Department of Health
San Lazaro Compound
Sta. Cruz, Manila

Dear Secretary Bengzon:

We wish to express our deep concern over the reported regulatory thrust of the Department as well as recent statements quoted in media that cast some of our members in an adversarial light.

We recognize the staggering problem in the health field resulting from the fact that the greater part of the population is not in the money economy, a problem that requires enormous efforts from a decent and well intentioned government.

The globally owned and operated manufacturers and marketers that operate here have an essential role to perform in the development of the whole Philippine economy. They are a vital ingredient in the efforts to raise the standard of living.

It is therefore our firm belief that the internationally affiliated pharmaceutical providers in the Philippines are part of the health care solution, and not a part of the health care problem.

The grant of broad rights of commercial endeavor to private groups has been a common feature in all nations that have attained prosperity. Experience in these economies has also shown that government intervention has worked best where it has supplemented instead of supplanted private activities.

It is therefore with some dismay that we hear proposals to use government power to closely control, widely prohibit, and minutely redirect private activities in the health sector that do not conform to a state sponsored master plan. And then, to read quotes attributed to you which apply to responsible corporate members of our business community the now famous cry of "tama na, palitan na" used in the past against a repressive regime.

This will have a chilling effect on the entire foreign business community and a devastating effect on the possibilities for job generating investments by foreign concerns.

If there has been a misunderstanding, we urge you to clarify matters and we stand ready to meet with you at your convenience to accomplish this.

Sincere regards,

A. Gordon Westly
President

24 June 1988

Mr. A. Gordon Westly
President
American Chamber of Commerce of the Philippines
Corinthian Plaza, 2nd Floor
Paseo de Roxas, Makati, Metro Manila

Dear Mr. Westley:

This is in reply to your letter of 31 May 1988.

The government's drug policy has been clearly enunciated time and time again, beginning with President Aquino's announcement on 30 April 1987. Its goals of assuring that our people get safe, effective, high quality and affordable drugs have been widely discussed. Our intentions regarding how we shall pursue such goals have been elaborated in many meetings. A key goal that we aim to achieve is the provision to both the physician and the public *basic, adequate and honest information as a basis for personal action* on drugs, Clearly, this is a hallmark of democracy. Around this goal, we seek to promote sound regulation, rational use of drugs, and basic national self-sufficiency.

One thing is clear to us: we cannot rely on your Chamber nor on your members *to take the initiative* to protect Filipino consumers, nor to develop an honest-to-goodness local pharmaceutical industry, nor to widen the access of poor Filipinos to drugs that they need. Because you are businessmen (and foreign), your primary goal is to ensure profit; that is to be expected. Contribution to our economy, national development and public good is secondary and definitely not ahead of corporate bottomlines.

Therefore, our task as a Government is to devise ways that would allow you to make your profit *only* when you respect our national interests, *only* when your activities serve the real needs of our people, and *only* when you truly contribute to our economy. Otherwise, you are only exploiting us and this should not continue. This is the task that we are addressing in the field of drugs and medicines: devising ways such that everyone can continue to do business *only* when the interests of the poor Filipino consumers are protected and promoted.

Multinational pharmaceutical companies may have a role in our economy. But left to their own accord, it is in their nature to maximize sales and profits, "even while the poorest, sickest and most remote people have virtually no access to good therapy; even while most pharmaceuticals prescribed bear scant relevance to the diseases of those who do have access and means; even while millions of people are unprotected from the profligate and haphazard use of ineffective or dangerous chemicals designated as medicines."(1)

Your letter says: leave the multinationals alone and they will be part of the solution. Well, your Chamber has been in the Philippines since 1902. (You style

yourself the first American Chamber of Commerce abroad.) What have your "internationally-affiliated pharmaceutical providers in the Philippines" done to change the situation? Eighty-six years after you set up your Chamber, we continue to be import dependent; no real technology transfer regarding basic manufacturing has happened. From this point of view, the famous cry of "Tama na, Palitan na" is appropriate when applied to this situation. Clearly the *status quo* is not acceptable.

Your members have no reason to complain about too much regulation in the Philippines. A simple straightforward comparison between the policies and procedures of the US FDA and our BFAD will show that the Philippine market for pharmaceuticals is a playground compared to the stringent regulations in the US. We are only doing what we should have done long ago: adopt the basic rules necessary to protect our consumers and apply these rules strictly and equitably.

I remember vaguely that Rhett Butler in "Gone with the Wind" noted that a fortune can be made in raping the land just as greater fortunes can be made in building a nation. We look to businessmen with an interest for the latter.

There are many investors who can see sound business prospects in honest-to-goodness reform that yield real benefits to a majority of Filipinos. We are confident that there are many astute investors who can see that expanding access to drugs via lower costs, better quality, honest information, and more appropriate use is a socially, as well as financially, superior business proposition than the present world of limited access, high costs, doubtful quality, misinformation, and irrational use. Local, multinational or even extraterrestrial business interests are welcome but this Government shall remain vigilant and forceful so that the ground rules protecting and promoting the public interest continue to be operative. The National Drug Policy provides those ground rules.

Very truly yours,

Alfredo R.A. Bengzon, MD
Secretary of Health

1. Fabricant SJ and Hirschhorn N (1987). Deranged distribution, perverse prescription, unprotected use: the irrationality of pharmaceuticals in the developing world. *Health Policy and Planning;* 2(3): 204-213.

NDP Update

It has been 16 months since the National Drug Policy was announced in 30 April 1987 by President Corazon C. Aquino. Great strides have been made. The following have been accomplished:

1. *Re-organization of BFAD.* The Bureau of Food and Drugs (BFAD), our government's key regulatory agency for pharmaceuticals, has been reorganized; a major strengthening program is underway to upgrade the capabilities of the staff through technical cooperation projects supported by the Japanese International Cooperation Agency (JICA), UNDP and WHO.
2. *Review of BFAD Systems.* Staff from the UP College of Pharmacy and the Department of Pharmacology of the UP College of Medicine have re-inforced the existing BFAD staff. These experts are at work in evaluating the current policies, standards, and procedures for product registration, licensing of sales establishments, and quality control in the laboratory.
3. *Delisting of Banned Drugs.* Upon the recommendation of the National Drug Committee, the BFAD has initiated the process to delist drugs that are banned, restricted, or withdrawn from other countries but are still being sold here. There are 18 categories of these drugs which include dipyrones, oral proteolytic enzymes, and chloramphenicol in fixed-dose combinations.
4. *Legislation on use of Generic names.* Both houses of Congress have proposed bills for the use of generic names in the labelling and prescribing of medicines. The Senate and Lower House have approved the final version of the Generics Act of 1988. President Corazon C. Aquino will sign the bill into law on 13 September 1988.
5. *Work on National Drug Formulary (NDF).* The National Drug Committee is conducting a systematic review of all drugs according to therapeutic categories. This work has already resulted in the identification of 265 drugs which have recommended to the BFAD for delisting. It will eventually result in a National Drug Formulary which will contain core and complementary lists of drugs officially sanctioned by the Department of Health for sale in the Philippines. This will be ready by the first quarter of next year.
6. *Master Plan for Pharmaceutical Development.* In line with the drive towards self-sufficiency, a study is being conducted with the United Nations Industrial Development Organization (UNIDO) to arrive at a plan for the production of pharmaceutical chemicals in the Philippines. Based on this plan, private investment will be invited to go into the production of raw materials and intermediates needed to produce drugs and medicines.
7. *Improvement in DOH procurement of medicines.* Cost-saving measures have resulted in a 30% rise in procurement for each peso spent. Procurement is presently based on a therapeutic list using generic nomenclature.
8. *Budgetary Outlay for the implementation of the NDP.* A budget to support the implementation of the National Drug Policy has been included for 1989.
9. *Management Committee to oversee implementation of the NDP.* A Committee headed by the Assistant Secretary for

Standards and Regulations has been formed to coordinate all efforts toward the implementation of the National Drug Policy.

Our hope is that this National Drug Policy will eventually remedy the gross imbalance in the Philippine pharmaceutical market where a strong supply side, which is controlled by multinational corporations and almost completely import-dependent, dominates an extremely weak demand side, which is a poorly-informed public that is dependent on health professionals who are invariably influenced by the aggressive and expensive marketing practices of pharmaceutical companies.

Oppositions to the NDP and the Generics Act have been manifested by drug companies and by the Board of Governors of the Philippine Medical Association. Letters of concern from two US senators and the President of the American Chamber of Commerce in the Philippines have been publicized as symbolic of the resistance of groups which wished to preserve the *status quo*.

The Department of Health seeks your support and the support of all sectors of society in the effort to implement the National Drug Policy. The NDP relates to the health of each and every Filipino and certainly deserves the cooperation of everyone.

Review of implementation
(As of August 31, 1988)

NDP Update

(Developments during September and October to date)

General Policy

1. President Cory Aquino signed the Generics Act into law last September 13, 1988. The following were present during the ceremonies: principal proponents Senator Orlando Mercado and Congressman Narciso Monfort; the leaders of Congress including Senate President Jovito Salonga and House Speaker Protempore Antonio Cuenco; members of the Cabinet and the Diplomatic Corps; and representatives of consumer groups, non-government orgnizations, industry, academic, and medical, pharmacy, and dental societies.

FOUR PILLARS

Quality Assurance

2. The BFAD is revising requirements, standards, systems and procedures for licensing of drug establishments and registration of drug products. The revised requirements and standards were the subjects of two separate consultations with drug manufacturers and drug outlets last September 30 and October 7.
3. The BFAD has accelerated the recruitment and training of BFAD technical personnel in dissolution testing, bioavailability and bioequivalence studies as well in the revised systems and procedures. These training programs are held here and abroad.
4. The BFAD has acquired a new dissolution testing apparatus.
5. One hundred sixty eight (168) out of the 265 products belonging to the list of banned, withdrawn or severely restricted in countries abroad, have been withdrawn from the local market.

Rational Drug Use

6. The National Drug Committee has completed the list of Core and Complementary drugs for two sections: the Central Nervous System and Musculo Skeletal System. There are a total of twenty two (22) sections of the Philippine National Drug Formulary. Five (5) other sections - Anti-infectives, Cardiovascular drugs, Diuretics, Respiratory Drugs and Anti-allergies - have passed the evaluations of external experts and are being finalized for approval by the Secretary of Health. The Philippine National Drug Formulary will be completed by March 1989.

Self-reliance

7. The draft Philippines-UNIDO Pharmceutical Industry Development Study Project Report has just been completed. It identifies five possible projects that will lead to local production of active ingredients. The project report will be reviewed by an independent panel of experts on October 27 and 28, 1988 in Vienna. Full-pledged feasibility studies on the most promising projects will follow.
8. The Cotabato Herbal Processing and Manufacturing Plant will be inaugurated by Pres. Cory Aquino on November 15. It has the capacity of producing 2 million tablets from medicinal plants per month.

   Two other Regional Herbal Processing and Manufacturing Plants in Tacloban, and Tuguegarao will start operating next year.

Tailored Procurement

9. To ensure that they meet the new BFAD requirements and standards the manufacturing plants of winning bidders for government drug procurement contracts are inspected and re-evaluated.
10. The Philippine National Drug Formulary and its various derivatives formularies for the primary, secondary and tertiary health care levels, are now going to be used strictly as the basis for drug procurement by government hospitals and institutions.

The National Drug Policy and the Generics Act Issues and Answers

1. On the capability of the Bureau of Food and Drugs to ensure the quality of drugs and medicines on the market.

Issue: The Bureau of Food and Drugs (BFAD) is not capable of ensuring the quality of the drugs and medicines being sold in the market. It does not have the manpower and facilities to test the thousands of products presently being sold.

Answer: This criticism was true of the old BFAD which was housed in a run-down building in the San Lazaro Compound. It did little to regulate the sale of drugs and medicines in the market. It merely acted as a compiler of paper requirements for the registration of products before sale to the public. This was the situation in the past.

Today we have a new BFAD. It has a modern US$12 million facility in Alabang equipped with all the modern equipment necesary.It has been undertaking training programs for its personnel so that they can competently tackle the job at hand. These training programs are under the auspices of the World Health Organization (WHO), the United Nations Development Program (UNDP), and the Japanese International Cooperation Agency (JICA). From July 7 to September 7, 1988, the BFAD suspended the registration of products and the licensing of drug establishments in order to streamline its systems and procedures.

The new BFAD has been strengthened by experts from the faculty of the University of the Philippines. These experts come from the College of Pharmacy and the College of Medicine's Department of Pharmacology. They work closely with Asst. Secretary Quintin Kintanar who is in charge of the implementation of the National Drug Policy and the Generics Act.

The staff of the new BFAD have accepted the challenge before them. They are, for instance, taking appropriate steps to delist unsafe and ineffective drugs presently in the market. They are also establishing rigorous registration requirements and strict standards of safety, efficacy and quality before any drug is allowed to be sold to the public.

2. On the delisting of drugs and medicine

Issue: All drugs and medicine on sale in the Philippines are registered with the BFAD and should therefore be considered safe and effective and should not be delisted.

Answer: This issue is raised by manufacturers whose products are under review for possible delisting. This issue offers testimony that the new BFAD is doing its job properly. Otherwise manufacturers would not complain.

Contrary to what is implied here, previous registration is no guarantee that a product is still considered safe and efficacious. It simply means that the manufacturer submitted the documents required for registration and satistfied the criteria of safety, efficacy, and quality at that time. But data and experience on drugs are not static. As more experiences are gathered, toxicities and lack of efficacy on therapeutic value are discovered resulting in registered drugs being banned, withdrawn or restricted. The BFAD is presently undertaking a process where drugs which are known to be unsafe and ineffective will be delisted. An example of such a product is dipyrone, an analgesic that is known to cause a deficiency of white blood cells, the first line of defense against infections.

3. On the effect of the Generics Act

Issue A: The Generics Act will result in the proliferation of fake and substandard drugs.

Answer A: This issue is raised by critics who fear that by using generic names in the labelling, prescribing and dispensing of medicines, we are removing the safeguards of safety and efficacy which are supposedly assured by brand marketing. The critics say that people will have no benchmarks of quality or manufacturer's responsibility without the use of brands.

This is not true for a number of reasons. First, manufacturers which produce generically-labelled drugs do so using the same processes used in the making of brand name drugs. Therefore a legitimate manufacturer will ensure the quality of its generically-labelled product. Second, all manufacturers will be properly screened by the BFAD as to its plant and manufacturing processes and the name of the manufacturers of the drug will appear on the label. No manufacturer can sell its product if it cannot pass BFAD requirements. Third, retail outlets will be regularly checked by the BFAD to ensure that retail outlets purchase its supplies only from BFAD-accredited manufacturers.

Critics tend to forget that fake and substandard drugs existed in the market even before the passage of the Generics Act. These fake items are most often copies of popular and expensive brand products and not of generics.

Issue B: The quality of medicine will fall with the use of generics names.

Answer B: This is not true as already explained above. There are no fundamental changes in manufacturing processes, only in the inclusion of generic names in labels.

We must remember that all medicine have generic names and to enforce the practice of using them is to bring back to medicine and pharmacy a sound, scientific approach. This is because a generic name immediately reveals the active substance of a medicine and what it is used for. For example, by saying bacampicillin, a practitioner or patient can know that the antibiotic, a variant of ampicillin, has been prescribed. A practitioner will not be confused by the brand name of which there are several for this drug.

Issue C: The Generics Act will not decrease the prices of medicines because promotions add only a small percentage to the cost of brand products. To lower prices, we should lower or remove taxes.

Answer C: For every commonly used medicines like analgesics and antibiotics, there already are branded and non-branded products available in the market. From a comparison of prevailing retail prices, one can easily see that non-branded products cost far less than the branded ones. The choice of a non-branded product over a branded product saves the consumer money by as much as 40-80%.

Since 95% of our raw materials for pharmaceutical production are imported, these are subject to tariffs. The solution is not to lower taxes which only serve to decrease government revenues, but to develop our local manufacturing capabilities so that the country import's less.

4. On Generic Prescribing by Physicians

Issue A: Physicians should have the prerogative to prescribe the brands that they favor. The Generics Act violates the physician's right to free choice.

Answer A: Those who say this do not understand the provisions of the law. Physicians are required by law-to write down the generic name of the medicine they are prescribing. They also can, if they wish, write down the brand they prefer.

The law actually encourages physicians to discuss with patients the economic considerations in the purchase of medicine. This is so, because, for every medicine, there are a whole range of products, both branded and non-branded. On the contrary, rather than violate the physician's right to free choice, the law safeguards both the physician's and consumer's right to choose the best medicine, all factors considered.

Issue B: Physicians should not be penalized for not using generic names. Penalizing physicians is outrageous and ridiculous.

Answer B: We know that most physicians will follow the law. For them, the discussion of penalties is superfluous. Penalties are for those who are undisciplined and incorrigible.

We can only restate here that the use of generic names in prescribing is good practice of medicine which has been adopted in many other countries. We urge all physicians to internalize this principle and uphold it in their practice.

Issue C: Generic names are difficult to remember. Should a physician be penalized if he cannot remember a generic name in an emergency situation?

Answer C: Those who say this overstate the argument against the use of generic names and underestimate the capacity of people to learn. Over time and constant usage, generic names will easily be remembered. Moreover, a simple list of commonly-used drugs with their generics names can easily be prepared by each practitioner.

Issue D: It is not practical to use generic names for products with fixed-dose combinations.

Answer D: This problem arises when a product contains 3-4 active ingredients. For example, some cough medicines contain a cough suppressant, mucolytic, antihistaminic etc. The BFAD will be discouraging such irrational formulations. There are experts who are reviewing what fixed-dose combinations are rational and will be allowed. Multi-active ingredient combinations which are justified on the basis of pharmacological principles and therapeutic advantages can also be given an official generic name, e.g. cotrimoxazole for the combination of trimethoprim and sulfamethoxazole.

5. On Generic Dispensing

Issue A: Products with the same generic names are not bioequivalent and should not be substituted.

Answer A: Studies have shown that if good manufacturing practices are followed, products with the same active ingredient attain comparable blood levels and achieve the desired therapeutic effect. In 224 bioequivalence studies done by the US FDA, the difference in blood levels achieved by generics and equivalent brand products averaged only 3-5%. The new BFAD is making sure that all manufacturers in the Philippine market follow good marketing practices. There are some medicines, like anticoagulants, psychotropic drugs, and cardiac medicine where the general rule of bioequivalence may not apply and here extra care should be undertaken when substituting. These cases are exceptional. The general principle of bioequivalence applies for most medicines.

Issue B: The Generics Act will allow unqualified persons (sales clerks) to do generic dispensing. This is risky business.

Answer B: Even without the Generics Act, the business of retailing has been risky since sales clerks have been dispensing medicine. The Generics Act has simply highlighted the deficiencies of the present system. The new BFAD is considering the requirement that all pharmacies and drugstore outlets hire pharmacists to professionalize the retail industry.

Proposed Provisions for Administrative Order on Implementation of R.A. 6675 (Generics Act of 1988) in the Department of Health

1. Roles of DOH in Implementation of R.A. 6675

1.1 DOH is one of the key government agencies that need to comply with the use of generic terminology or generic names in all transactions related to purchasing, prescribing, dispensing and administering of drugs and medicines (Sec. 6(a))

1.2 DOH is also one of the key government agencies that need to promote use of generic terminology through public information and continuing education of health professionals (Sec. 11)

1.3 DOH is also tasked with facilitating the implementation of the law, and the compliance of concerned entities with the law's provisions (Sec. 9 and 12 (c))

Thus, DOH needs to administer its affairs to comply with the law, act as as an advocate of the law's provisions and principles, and perform as an arbiter of issues regarding details of its implementation.

2. Structure of Implementing Organization

2.1 At the central level, the National Drug Policy Implementation Team created in A.O. No. 46 headed by the Assistant Secretary for NDP is the unit responsible for drafting recommendations for policy guidelines and operational instructions on all matters regarding implementation of R.A. 6675. These recommendations shall be reviewed by the Executive Committee for National Field Operations. The Secretary shall approve any issuance on this matter.

In the bi-monthly meeting of all regions in the national staff conference, the Assistant Secretary for NDP shall be allocated time at his request to take up matters of interest in relation to implementation of R.A. 6675.

2.2 At the field level, the following officials are tasked with executing the DOH roles in implementing R.A. 6675 at their respective areas or institutions.

2.2.1 The Regional Health Directors for all DOH agencies in the region.

2.2.2 The Provincial Health Officers for all DOH agencies in the province.

2.2.3 The Chiefs of District Hospitals in their respective hospitals and catchment areas.

2.2.4 The Chiefs of National Medical Centers, special research centers and hospitals, regional medical centers and regional hospitals in their respective institutions.

2.3 Specialized committees to assist the above mentioned responsible officials at the field level shall be created. The following instructions on this matter are pertinent.

2.3.1 Regional Level: A Technical Committee for Drugs and Medicine should be organized at the Regional Health Office as per A. O. No. 28, series 1987 including attachment on regional bulk procurement guidelines. Each Regional Health Office shall report on the composition of this committee at the region and on its readiness to assume functions expected as per Annex A.

2.3.2 Provincial Level: A Therapeutic Committee should be organized at each Integrated Provincial Health Office. Each PHO shall report on the composition of its committee at the province and on its readiness assume functions expected as per Annex A.

2.3.3 District Hospital Level: The Chief of Hospital, a senior resident physician, one rural health physician, the chief nurse and the hospital pharmacist shall constitute the district health office's Therapeutic Committee. Each District Hospital shall report on the composition of its committee at the district and on its readiness to assume functions expected as per Annex A.

2.3.4 Special/Regional Hospital Level: A Therapeutic Committee composed of the Chief of Professional Medical Staff, three or more clinical department heads, the physician responsible for training, and the hospital pharmacist shall be organized.

Each chief of hospital shall report on the composition of its committee and on its readiness to assure the functions expected as per Annex A.

2.4 At each region and special hospital, the Regional Director, or Chief of Hospital (as the case may be) shall designate an NDP operations officer. This compliance officer will be tasked with gathering the data on that agency's compliance with all issued instructions such as: (a) organization and regular functions of Therapeutic Committees or analogous bodies; (b) issuance of internal orders and instructions on this matter; (c) reports of violations and successes; (d) specific progress or setbacks.

3. Procurement

3.1 All heads of agencies procuring drugs and medicines whether from (a) regular budget (b) local aid (c) trust funds for drugs and medicines shall be responsible for specifying all drug and medicine items in their generic names in the RIV's, Biddings, PO's and other procurement documents including disbursement documents. This shall cover both regular procurement as well as emergency procurement.

3.2 Any question on generic terminology shall be referred to the Therapeutic Committee or analogous body. If this cannot be resolved, the matter shall be immediately referred to BFAD. Upon referral, the Therapeutic Committee concerned can temporarily decide on the matter until a response from the BFAD is received. This refers to cases when there is some debate on the appropriate generic name (e.g. fixed dose combination drugs)

4. Prescribing and Ordering

4.1 All prescriptions and orders in DOH facilities shall be made in generic terminology. Brand names maybe written but in all cases the generic name of the active ingredient shall be stated.

4.2 All areas and institutions shall set a specific date for adopting mandatory generic prescribing. Prior to such date, voluntary generic prescribing will be encouraged. Information and explanations should be provided to all concerned so that generic prescribing can be facilitated. On the date when mandatory generic prescribing takes effect, there should be launching activities to inform both the public and the professionals.

5. Dispensing and Administering

5.1 All dispensing units (pharmacies, clinics, other service outlets) of the DOH shall adopt generic dispensing, i.e. filling doctor's prescriptions and orders on the basis of the specified generic name, dose level, dosage form and delivery mode. If no drug preparation is available to comply with what was generically prescribed, the prescribing physician shall be duly informed so that the the prescription can be changed to one that can be filled.

5.2 Nurses in hospitals shall use generic terminology in patient charts and all records of drugs and medicines used.

5.3 Each area or institution shall similarly set the date when generic dispensing shall become mandatory. Necessary preparations to inform all concerned and clarify all issues and questions should be undertaken.

6. Public Information

6.1 The Heads of Agencies shall take sufficient steps to inform the public about the measures being adopted by the DOH to implement R.A. 6675. Whenever public complaints arise, the Heads of agencies shall take action to resolve such complaints.

6.2 The Public Information and Health Education Service shall prepare a checklist of informational materials necessary to inform the public. This unit shall also insure that those materials identified in the checklist are available for distribution or reproduction at all DOH agencies. PIHES shall consult heads of agencies on the materials that they believe are necessary for proper public information.

7. Professional Promotion

7.1 The heads of agencies, assisted by their Therapeutic Committees, shall undertake promotional activities among DOH personnel, particularly physicians and nurses. These promotional activities should (a) clarify the provisions of the law; (b) explain the reasons for generic terminology in drug use; (c) answer the most common misinformation, apprehensions and complaints.

7.2 The Public Information and Health Education Service shall make available to all Therapeutic Committees the necessary technical information and literature to undertake proper professional promotion of generic use.

8. Sharing of Technical Resources

8.1 The operations/monitoring officer for the region shall identify provinces and districts where there is a lack of technically prepared physicians for generic drug use implementation. In these cases, he shall recommend mechanisms for sharing technical resources such as regular visits by a better prepared doctor to assist Therapeutic Committees or lectures and workshops supported by national facilities.

ANNEX A: Functions of Therapeutic Committees or Analogous Bodies in DOH

The Technical Committee for Drugs and Medicines at the regional level the Therapeutic Committees at the PHO's and District Hospitals, and the Hospital Pharmacy and Therapeutic Committees at special and regional hospitals and medical centers shall have the following functions:

1. Based on the DOH Drug Formulary (for Hospitals and RHU's), the committee shall regularly maintain a list, specified in generic terminology, of the drugs that the region, province or hospital will stock, use, buy or prescribe. It should start with the DOH Formulary and choose based on its deliberations and agreements. The most recently updated list shall be circulated to (a) procurement and supply units (b) pharmacies and (c) medical staffs.
2. The DOH formulary shall be used as basis in drug selection, utilization, procurement, and stocking policies such as how to allocate resources for different generic items for drugs; how to resolve problems regarding drug quality; how to evaluate drug information; how to facilitate generic prescribing and dispensing; how to assure proper distribution of drug supplies within the area or institution; as well as similar concerns.
3. Evaluate and recommend appropriate action concerning:
   a) requests for inclusion or exclusion of any drug for use in the area or institution
   b) reports of adverse drug reactions or other problems related to safety, efficacy or quality of drugs
4. Identify and define information, education or training needs of the area or institution on the matter of the implementation of R.A. 6675, the national drug policy, pharmacological science and drug use. Specify such needs in terms of short term or continuing, selective or general, types of personnel needed, materials and support required.
5. Plan an orderly, systematic and thorough process of institutionalizing rational drug use, marked by medium and long term stages such as: a)adoption of generic terminology, b) identification of specific problems, hindrances, obstacles and difficulties to the widespread use of generic terminology c) elimination of these factors, d) promotion of rational use of drugs.

S. No. 453
H. No. 10900

Republic of the Philippines
CONGRESS OF THE PHILIPPINES
Metro Manila

Second Regular Session

Begun and held in Metro Manila, on Monday, the twenty-fifth day of July, nineteen hundred and eighty-eight

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[REPUBLIC ACT No. 6675]

AN ACT TO PROMOTE, REQUIRE AND ENSURE THE PRODUCTION OF AN ADEQUATE SUPPLY, DISTRIBUTION, USE AND ACCEPTANCE OF DRUGS AND MEDICINES IDENTIFIED BY THEIR GENERIC NAMES

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled :

SECTION 1. *Title.* - This Act shall be known as the Generics Act of 1988.

SEC. 2. *Statement of Policy.* - It is hereby declared the policy of the State:

To promote, encourage and require the use of generic terminology in the importation, manufacture, distribution, marketing, advertising and promotion, prescription and dispensing of drugs;

To ensure the adequate supply of drugs with generic names at the lowest possible cost and endeavor to make them available for free to indigent patients;

To encourage the extensive use of drugs with generic names through a rational system of procurement and distribution;

To emphasize the scientific basis for the use of drugs, in order that health professionals may become more aware and cognizant of their therapeutic effectiveness; and

To promote drug safety by minimizing duplication in medications and/or use of drugs with potentially adverse drug interactions.

SEC. 3. *Definition of Terms.* - The following terms are herein defined for purposes of this Act:

(1) "Generic Name or Generic Terminology" is the identification of drugs and medicines by their scientifically and internationally recognized active ingredients or by their official generic name as determined by the Bureau of Food and Drugs of the Department of Health.

(2) "Active Ingredient" is the chemical component responsible for the claimed therapeutic effect of the pharmaceutical product.

(3) "Chemical Name" is the description of the chemical structure of the drug or medicine and serves as the complete identification of a compound.

(4) "Drug Product" is the finished product form that contains the active ingredients, generally but not necessarily in association with inactive ingredients.

(5) "Drug Establishment" is any organization or company involved in the manufacture, importation, repacking and/or distribution of drugs or medicines.

(6) "Drug Outlets" means drugstores, pharmacies, and any other business establishments which sell drugs or medicines.

(7) "Essential Drugs List" or "National Drug Formulary" is a list of drugs prepared and periodically updated by the Department of Health on the basis of health conditions obtaining in the Philippines as well as on internationally accepted criteria. It shall consist of a core list and a complementary list.

(8) "Core List" is a list of drugs that meets the health care needs of the majority of the population.

(9) "Complementary List" is a list of alternative drugs used when there is no response to the core essential drug or when there is a hypersensitivity reaction to the core essential drug or when, for one reason or another, the core essential drug cannot be given.

(10) "Brand Name" is the proprietary name given by the manufacturer to distinguish its product from those of competitors.

(11) "Generic Drugs" are drugs not covered by patent protection and which are labeled solely by their international non-proprietary or generic name.

SEC. 4. *The Use of Generic Terminology for Essential Drugs and Promotional Incentives.* - (a) In the promotion of the generic names for pharmaceutical products, special consideration shall be given to drugs and medicines which are included in the Essential Drugs List to be prepared within one hundred eighty (180) days from approval of this Act and updated quarterly by the Department of Health on the basis of health conditions obtaining in the Philippines as well as on internationally accepted criteria.

(b) The exclusive use of generic terminology in the manufacture, marketing and sales of drugs and medicines, particularly those in the Essential Drugs List, shall be promoted through such a system of incentives as the Board of Investments jointly with the Department of Health and other government agencies as may be authorized by law, shall promulgate in accordance with existing laws, within one hundred eighty (180) days after approval of this Act.

SEC. 5. *Posting and Publication.* - The Department of Health shall publish annually in at least two (2) newspapers of general circulation in the Philippines the generic names, and the corresponding brand names under which they are marketed, of all drugs and medicines available in the Philippines.

SEC. 6. *Who Shall Use Generic Terminology.* - (a) All government health agencies and their personnel as well as other government agencies shall use generic terminology or generic names in all transactions related to purchasing, prescribing, dispensing and administering of drugs and medicines.

(b) All medical, dental and veterinary practitioners, including private practitioners, shall write prescriptions using the generic name. The brand name may be included if so desired.

(c) Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. In the case of brand name products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials.

(d) Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets and stores, shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately exercise his option. Within one (1) year after approval of this Act, the drug outlets referred to herein, shall post in conspicuous places in their establishments, a list of drug products with the same generic name and their corresponding prices.

SEC. 7. *Provision on Quality, Manufacturer's Identity and Responsibility.* - In order to assure responsibility for drug quality in all instances, the label of all drugs and medicines shall have the following: name and country of manufacture, dates of manufacture and expiration. The quality of such generically labeled drugs and medicines shall be duly certified by the Department of Health.

SEC. 8. *Required Production.* - Subject to the rules and regulations promulgated by the Secretary of Health, every drug manufacturing company operating in the Philippines shall be required to produce, distribute and make available to the general public the medicine it produces, in the form of generic drugs.

SEC. 9. *Rules and Regulations.* - The implementation of the provisions of this Act shall be in accordance with the rules and regulations to be promulgated by the Department of Health. Rules and regulations with penal sanctions shall be promulgated within one hundred eighty (180) days after approval of this Act and shall take effect fifteen (15) days after publication in the *Official Gazette* or in two (2) newspapers of general circulation.

SEC. 10. *Authority to Import.* - Within three (3) years from the effectivity of this Act, extendible by the President for another two (2) years and during periods of critical shortage and absolute necessity, the Department of Health is hereby authorized to import raw materials of which there is a shortage for the use of Filipino -owned or controlled drug establishments to be marketed and sold exclusively under generic nomenclature. The President may authorize the importation of raw materials tax and duty-free. The Secretary of Health shall ensure that the imported raw materials are allocated fairly and efficiently among Filipino-owned or controlled drug establishments.' He shall submit to the Office of the President and to Congress a quarterly report on the quantity, kind and value of the raw materials imported.

SEC. 11. *Education Drive.* - The Department of Health jointly with the Department of Education, Culture and Sports, Philippine Information Agency and the Department of Local Government shall conduct a continuous information campaign for the public and a continuing education and training for the medical and allied medical professions on drugs with generic names as an alternative of equal efficacy to the more expensive brand name drugs. Such educational campaign shall include information on the illnesses or symptoms which each generically named drug is supposed to cure or alleviate, as well as its contraindications. The Department of Health with the assistance of the Department of Local Government and the Philippine Information Agency shall monitor the progress of the education drive, and shall submit regular reports to Congress.

SEC. 12. *Penalty.* - A) Any person who shall violate Section 6(a) or 6(b) of this Act shall suffer the penalty graduated hereunder, viz:

(a) for the first conviction, he shall suffer the penalty of reprimand which shall be officially recorded in the appropriate books of the Professional Regulation Commission.

(b) for the second conviction, the penalty of fine in the amount of not less than two thousand pesos (P2,000.00) but not exceeding five thousand pesos (P5,000.00) at the discretion of the court.

(c) for the third conviction, the penalty of fine in the amount of not less than five thousand pesos (P5,000.00) but not exceeding ten thousand pesos (P10,000.00) and suspension of his license to practice his profession for thirty (30) days at the discretion of the court.

(d) for the fourth and subsequent convictions, the penalty of fine of not less than ten thousand pesos (P10,000.00) and suspension of his license to practice his profession for one year or longer at the discretion of the court.

B) Any juridical person who violates Section 6 (c), 6 (d), 7 or 8 shall suffer the penalty of a fine of not less than five thousand pesos (P5,000.00) nor more than ten thousand pesos (P10,000.00) and suspension or revocation of license to operate such drug establishment or drug outlet at the discretion of the Court: *Provided*, That its officers directly responsible for the violation shall suffer the penalty of fine and suspension or revocation of license to practice profession, if applicable, and by imprisonment of not less than six (6) months nor more than one (1) year or both fine and imprisonment at the discretion of the Court: and *Provided, further*, That if the guilty party is an alien, he shall be *ipso facto* deported after service of sentence without need of further proceedings.

C) The Secretary of Health shall have the authority to impose administrative sanctions such as suspension or cancellation of license to operate or recommend suspension of license to practice profession to the Professional Regulation Commission as the case may be for the violation of this Act.

SEC. 13. *Separability Clause*. - If any provision of this Act is declared invalid, the remainder or any provision hereof not affected thereby shall remain in force and effect.

SEC. 14. *Repealing Clause*. - The provisions of any law, executive order, presidential decree or other issuances inconsistent with this Act are hereby repealed or modified accordingly.

SEC. 15. *Effectivity.* - This Act shall take effect fifteen (15) days after its complete publication in the *Official Gazette* or two (2) newspapers of general circulation.

Approved,

RAMON V. MITRA
Speaker of the House of Representatives

JOVITO R. SALONGA
President of the Senate

This Act which is a consolidation of Senate Bill No. 453 and House Bill No. 10900 was finally passed by the Senate and the House of Representatives on August 25, 1988 and August 31, 1988, respectively.

QUIRINO D. ABAD SANTOS, JR.
Secretary of the House of Representatives

EDWIN P. ACOBA
Secretary of the Senate

Approved: September 13, 1988

CORAZON C. AQUINO
President of the Philippines

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