

4. プロジェクト・デザイン・マトリックス (PDM)

4-1 (英語版) プロジェクト・デザイン・マトリックス (PDM)

別添 4-1: (英語版)プロジェクト・デザイン・マトリックス(PDM)

**Project Title:** The Project for the Preparation and Publication of the Philippine Pharmacopeia in the Republic of the Philippines  
**Target Area:** Philippines  
**Project Period:** April 16, 2002 to April 15, 2005  
**Target Group:** DOH-BFAD, Pharmaceutical Industry, Schools of Pharmacy  
**Date of Preparation:** April 16, 2002

Narrative Summary	Objectively Verifiable Indicators	Means of Verification	Important Assumptions
<p><b>Overall Goal</b></p> <ul style="list-style-type: none"> <li>Improve the safety, efficacy and quality of pharmaceutical products and herbal medicines for the promotion of the health and safety of the people.</li> </ul>	<ul style="list-style-type: none"> <li>Reduction in the number of low quality drug products in the local market</li> </ul>	<ul style="list-style-type: none"> <li>Monitoring of the quality of drug products in drug outlets throughout the country</li> </ul>	<ul style="list-style-type: none"> <li>Inclusion in the DOH priority areas of development</li> <li>Enactment of law adopting the Philippine Pharmacopeia as an official national book of standards</li> </ul>
<p><b>Project Purpose</b></p> <ul style="list-style-type: none"> <li>All monographs in the First Edition of the Philippine Pharmacopeia are used as official national standards of pharmaceutical products and herbal medicines by concerned organizations and parties.</li> </ul>	<ul style="list-style-type: none"> <li>Major pharmaceutical companies, schools of pharmacy, drugstores and hospital pharmacies use the standard monographs in the Philippine Pharmacopeia as a reference book.</li> </ul>	<ul style="list-style-type: none"> <li>Survey of pharmaceutical industry to assess extent of use of established standards</li> </ul>	<ul style="list-style-type: none"> <li>Continued availability of budget and research funds</li> </ul>
<p><b>Outputs</b></p> <ol style="list-style-type: none"> <li>The monographs of pharmaceutical products and herbal medicines are prepared, validated and finalized in accordance with established monograph format and contents with the following components: <ul style="list-style-type: none"> <li>Definition and statement of purity or potency</li> <li>Quality test parameters</li> <li>Analytical procedures and test methods</li> <li>Acceptance range/limits for each test parameter</li> <li>Standardized characteristics of Philippine medicinal plants</li> </ul> </li> <li>The following general chapters are completed and finalized: <ul style="list-style-type: none"> <li>General Information</li> <li>General Notices and Requirements</li> <li>General Methods of Analysis</li> <li>General Rules for Preparations</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>To complete standard monographs of 30 pharmaceutical products and 30 herbal medicines by April, 2004</li> <li>To finalize by April, 2004</li> <li>To prepare by April, 2004</li> <li>To issue DOH's Administrative by December, 2004</li> <li>To conduct information dissemination campaigns</li> </ol>	<ol style="list-style-type: none"> <li>Copy of standard monographs</li> <li>Copy of the General Chapters</li> <li>Copy of final manuscript</li> <li>Copy of Administrative Order</li> <li>Record of dissemination campaign</li> <li>Organizational chart of DOH-BFAD</li> </ol>	<ul style="list-style-type: none"> <li>Philippine Pharmacopeial Organization continues to be functional.</li> </ul>

<p>- Reagents and Solutions</p> <p>- Tables and Indices</p> <p>3. The final manuscript of the Philippine Pharmacopeia is prepared</p> <p>4. All monographs in the First Edition of the Philippine Pharmacopeia are adopted as national official reference by Administrative Order of Department of Health</p> <p>5. Concerned parties are informed about the Philippine Pharmacopeia and understand the importance of Pharmacopeia</p> <p>6. A network of professionals in the fields of pharmacy education, industry and regulations who will ensure the continued development of the Philippine Pharmacopeia is established and institutionalized.</p>	<p>6. To institutionalize the Philippine Pharmacopeia Organization in DOH-BFAD by Dec., 2004</p>	
<p><b>Activities</b></p> <p>1-1. Preparation and establishment of the following component of a monograph through the conduct of literature research and/or laboratory research activities:</p> <ul style="list-style-type: none"> <li>- Definition and statement of purity or potency</li> <li>- Quality test parameters</li> <li>- Analytical procedures and test methods</li> <li>- Acceptance range/limits for each test parameter</li> <li>- Standardized characteristics of Philippine medicinal plant</li> </ul> <p>1-2. Conduct of applicability testing of analytical procedures</p>	<p><b>Inputs</b> (Japanese Side)</p> <p>1. Expert Assignment Scheme: &lt;Long Term Expert&gt; 1) Pharmacopeial Development &lt;Short Term Expert&gt; 1) Crude Drug 2) Chemical Analysis</p>	<p>(Philippine Side)</p> <p>1. Provision of Land and Facilities</p> <p>2. Assignment of counterpart staff 1) Project Manager 2) Pharmaceutical / Chemical Analysis</p> <ul style="list-style-type: none"> <li>• Counterpart staff will continue to work for project</li> <li>• Concerned parties will cooperate to the project</li> </ul>

<p>1-3. Conduct of validation tests of analytical procedures by three reference laboratories</p> <p>1-4. Preparation of Reference Standards for pharmaceutical products and medicinal plants</p> <p>1-5. Drafting of standard monographs in accordance with established monograph format and contents</p> <p>1-6. Presentation of draft monographs to the Steering Committee and Executive Board for approval</p> <p>2. Completion and finalization of the general chapters</p> <p>3. Conduct of a series of meetings to discuss about the manuscript among three working groups and develop the final manuscript of the Philippine Pharmacopeia</p> <p>4. Process the monographs in the final manuscript of the Philippine Pharmacopeia First Edition to be authorized by Administrative Order</p> <p>5. Conduct of information dissemination campaigns to all parties that will be affected by the Philippine Pharmacopeia</p> <p>6-1. Establishment of a network of professionals to ensure better collaboration for the continued development of the Philippine Pharmacopeia</p> <p>6-2. Development of proposal to be submitted to Department of Budget and Management for incorporating the Philippine Pharmacopeia Organization into BFAD structure</p>	<p>3) General Considerations or Administrative</p> <p>2. Equipment Provision Scheme</p> <ul style="list-style-type: none"> <li>• To provide at its own expense such machinery equipment and other materials necessary for implementation of the Project as listed in ANNEX 3*.</li> </ul> <p>3. Counter Part Training Scheme:</p> <ul style="list-style-type: none"> <li>• Two or three Philippine counterpart(s) to be received annually in Japan</li> </ul>	<p>4) Herbal Medicines / Crude Drug Analysis</p> <p>5) Reference Standard Establishment</p> <p>6) Administration</p> <p>3. Local Cost:</p> <ul style="list-style-type: none"> <li>• 3,000,000 pesos per year</li> </ul>	<p><b>Preconditions</b></p> <ul style="list-style-type: none"> <li>• The policy direction of DOH to establish the Philippine Pharmacopeia will not be changed.</li> </ul>
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別添 4-2:(日本語版)プロジェクト・デザイン・マトリックス(PDM)

プロジェクト名: ファイリピン薬局プロジェクトフェーズ2  
 ファイリピン  
 対象地域: 2002年4月16日～2005年4月15日  
 協力期間: ファイリピン保健省食品医薬品局 (BFAD)、製薬企業、大学薬学部  
 ターゲットグループ: 2002年4月16日  
 作成日:

プロジェクトの要約	指標	指標の入手手段	外部条件
<p><b>上位目標:</b></p> <ul style="list-style-type: none"> <li>国民の健康な生活を確保すべく医薬品 (近代薬と伝統薬) の品質・安全性・有効性を改善する</li> </ul>	<ul style="list-style-type: none"> <li>ファイリピン国内市場からの低い品質の医薬品の減少数</li> </ul>	<ul style="list-style-type: none"> <li>全国の医薬品販売店で販売される医薬品の品質モニタリング</li> </ul>	<ul style="list-style-type: none"> <li>保健省の優先開発戦略として挙げられる</li> <li>ファイリピン薬局方を国家の標準規格書として承認する法が制定される</li> </ul>
<p><b>プロジェクト目標:</b></p> <ul style="list-style-type: none"> <li>ファイリピン薬局方第1版の医薬品各条が医薬品 (近代薬と伝統薬) の国家標準規格として関連組織・団体に使用される</li> </ul>	<ul style="list-style-type: none"> <li>主要な製薬企業、大学薬学部、薬局、病院薬剤部がファイリピン薬局方を参照資料として使用する</li> </ul>	<ul style="list-style-type: none"> <li>製薬企業を対象とした標準規格の使用状況調査</li> </ul>	<ul style="list-style-type: none"> <li>予算が継続的に割り当てられる</li> </ul>
<p><b>アウトプット:</b></p> <ol style="list-style-type: none"> <li>医薬品各条 (近代薬と伝統薬) が確立された定型に従って作成される (下記の項目を含む)             <ul style="list-style-type: none"> <li>純度 (もしくは効力) に関する定義と記述</li> <li>定性試験の要素・条件</li> <li>分析手順と試験方法</li> <li>試験条件の許容範囲</li> <li>ファイリピン伝統薬の標準的な性質</li> </ul> </li> <li>通則、総則、試験法などの一般情報に関する章が作成される (下記の項目を含む)             <ul style="list-style-type: none"> <li>参考情報</li> <li>通則</li> <li>一般試験法</li> <li>製剤総則</li> <li>試薬・試液</li> <li>表と索引</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>2004年4月までに、30種の近代薬と30種の伝統薬を記載した医薬品各条が作成される</li> <li>2004年4月までに作成される</li> <li>2004年4月までに作成される</li> <li>2004年12月までに保健省の省令が発令される</li> <li>情報共有のためのキャンペーンが実施される</li> <li>2004年12月までに、ファイリピン薬局方組織がBFAD内で制度化される</li> </ol>	<ol style="list-style-type: none"> <li>医薬品各条の原稿</li> <li>一般情報に関する章の原稿</li> <li>最終原稿</li> <li>省令文書</li> <li>情報共有キャンペーンの記録</li> <li>BFADの組織図</li> </ol>	<ul style="list-style-type: none"> <li>ファイリピン薬局委員会が機能し続ける</li> </ul>

<p>3. フィリピン薬局方の最終原稿が作成される</p> <p>4. フィリピン薬局方第1版が保健省の省令で承認される</p> <p>5. 関連団体の間でフィリピン薬局方とその重要性が周知される</p> <p>6. フィリピン薬局方の持続的な発展を担う専門家(教育機関・企業・規制機関)のネットワークが確立し制度化される</p>	<p><b>活動:</b></p> <p>1-1. 文献調査や試験の実施により、医薬品各条の以下の項目を作成する:</p> <ul style="list-style-type: none"> <li>● 純度(もしくは効力)に関する定義と記述</li> <li>● 定性試験の要素・条件</li> <li>● 分析手順と試験方法</li> <li>● 試験条件の許容範囲</li> <li>● フィリピン伝統薬の標準的な性質</li> </ul> <p>1-2. 分析手順・手法の適用試験を実施する</p> <p>1-3. 3つの試験室で分析手順・手法のバリデーション試験を実施する</p> <p>1-4. 近代薬と伝統薬の標準品を準備する</p> <p>1-5. 確立されたフォーマットに従って医薬品各条をドラフトする</p> <p>1-6. 医薬品各条ドラフトを審議会に提出し、承認を得る</p> <p>2. 通則や総則など一般情報に関する章を完成させる</p> <p>3. 3つの作業委員会(TWG)での一連の会議を通して、フィリピン薬局方の最終原稿を作成する</p> <p>4. フィリピン薬局方第1版について、省令での国家承認を得る</p> <p>5. フィリピン薬局方に関連する団体や機関に対し、薬局方の情報を普及させるための活動を実施する</p> <p>6-1. フィリピン薬局方を継続的に改定するための専門家によるネットワークを確立する</p> <p>6-2. フィリピン薬局方組織をBFAD内に組み入れるための提案書を作成し、予算・運営局に提出する</p>	<p><b>投入:</b> (日本側)</p> <p>1. 専門家派遣: &lt;長期専門家&gt; 1) 薬局方制定 &lt;短期専門家&gt; 1) 生薬 2) 化学分析 3) 薬局方公布体制</p> <p>2. 機材供与: プロジェクト実施に必要な各種器具・機材</p> <p>3. 本邦研修: 年間2~3人のプロジェクトカウンセラー</p>	<p>(フィリピン側)</p> <p>1. プロジェクト施設・設備</p> <p>2. カウンターパート配置: 1) プロジェクト・マネージャー 2) 近代薬分析 4) 伝統薬分析 5) 標準品開発 6) 薬局方行政</p> <p>3. 現地業務費: ● 年間300万ペソ</p>	<ul style="list-style-type: none"> <li>● カウンターパートがプロジェクト業務に継続的に従事する</li> <li>● 関連団体がプロジェクトに協力する</li> </ul> <p><b>前提条件:</b></p> <ul style="list-style-type: none"> <li>● フィリピン薬局方制定に向けた保健省の政策が変更されない</li> </ul>
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5. 評価グリッド

別添 5: 評価グリッド

	評価設問		判断基準・方法	必要な情報・データ	情報源・調査方法（長期専門家への聞き取りは全項目で実施）	
	大項目	小項目				
妥当性	プロジェクトはファイリピン国家のニーズに合致しているか	プロジェクトは国家の薬事を取り巻く問題点に対処することを主眼としているか	-	ファイリピンの薬事を取り巻く問題点	資料レビュー 保健省関係者への聞き取り BFAD 関係者への聞き取り 製薬企業関係者への聞き取り	
		薬局方に収載された医薬品の品目、数量は適切か	資料や聞き取り調査結果を基にした定性的評価	薬局方第1版 BFAD 関係者による評価 製薬企業関係者による評価 大学薬学部関係者による評価	資料レビュー BFAD 関係者への聞き取り 製薬企業関係者への聞き取り 大学薬学部関係者への聞き取り	
	ファイリピンの開発政策・保健政策との整合性はあるか	-	-	ファイリピンの開発政策・保健政策文書	資料レビュー 保健省関係者への聞き取り	
		日本の援助政策との整合性はあるか	-	-	「JICA 国別援助実施計画」 日本薬局方や薬事行政に関する情報	資料レビュー JICA 関係者への聞き取り 資料レビュー
	有効性	プロジェクト目標は達成されたか（達成される見込みか）	プロジェクト目標、指標は適切か	コンサルタントによる専門的見地からの判断	プロジェクトの PDM	資料レビュー
			プロジェクトは、プロジェクト終了時まで主要な製薬企業で使われるようになるか	主要な製薬会社で薬局方第1版を使っている割合	薬局方の配布リスト 製薬企業関係者の証言 医薬品登録の申請書	資料レビュー BFAD 関係者への聞き取り 製薬企業関係者への聞き取り
		プロジェクトは、プロジェクト終了時まで主要な製薬企業で使われるようになるか	大学薬学部の中で薬局方第1版を使っている割合	薬局方の配布リスト 大学薬学部関係者の証言 薬学部のカリキュラム	資料レビュー BFAD 関係者への聞き取り 大学薬学部関係者への聞き取り	

	薬局方第1版は、プロジェクト終了時まで薬局・病院薬剤部で使われるようになるか	薬局・病院薬剤部がフリーピン薬局方を所持するように定めた公式文書の存在	● 関連法・文書	● 資料レビュー
効 率 性	プロジェクト目標達成を阻害・促進した要因はあるか	—	● プロジェクト目標達成を促進・阻害した要因	● BFAD関係者への聞き取り ● 製薬企業への聞き取り ● 大学薬学部への聞き取り
	投入の量・質・タイミングは適正だったか	長期・短期専門家はプロジェクトに求められている専門性、資質を満たしていたか	● 専門家の経歴書 ● カウンターパートによる評価	● 資料レビュー ● カウンターパートへの聞き取り
		長期専門家派遣の人数、派遣日数、タイミングは適切だったか	● 専門家の報告書 ● カウンターパートによる評価	● 資料レビュー ● カウンターパートへの聞き取り
		供与機材はタイミングよく投入されたか	● 機材供与の記録文書 ● 機材供与先の関係者による評価	● 資料レビュー ● BFAD関係者への聞き取り
		投入された供与機材の規模、質は適正だったか	● 機材供与の記録文書 ● 機材供与先の関係者による評価	● 資料レビュー ● BFAD関係者への聞き取り
		活用されていない供与機材はないか	● 機材供与の記録文書 ● 機材供与先の関係者による評価	● 資料レビュー ● BFAD関係者への聞き取り
		研修期間、内容は適正だったか	● 研修の報告書 ● 研修受講者による評価	● 資料レビュー ● 研修受講者への聞き取り
	本邦・第三国研修は適正だったか	研修で得た知識・技術は帰国後に活用されているか	● 研修の報告書 ● 研修受講者による評価	● 資料レビュー ● 研修受講者への聞き取り
	外部条件・前提条件による影響はあったか	カウンターパートは協力的だったか	● 長期専門家による評価 ● プロジェクトマネージャーによる評価	● BFAD関係者への聞き取り
		カウンターパートは職場にとどまっているか	● 長期専門家による評価 ● BFAD関係者による評価 ● カウンターパートリスト	● 資料レビュー ● BFAD関係者への聞き取り
アウトプットの達成を阻害・促進した要因はあるか	医薬品各条(近代薬・伝統薬)を作成する過程を阻害・促進する要因はあったか	● 薬局方第1版 ● 長期専門家の証言 ● BFAD関係者の証言 ● バリデーション試験委託先の証言	● 資料レビュー ● BFAD関係者への聞き取り ● バリデーション試験委託先への聞き取り	

				<ul style="list-style-type: none"> <li>● 薬局方第1版</li> <li>● 長期専門家の証言</li> <li>● BFAD 関係者の証言</li> <li>● 関連する省令のレビュー</li> <li>● 長期専門家の証言</li> <li>● BFAD 関係者の証言</li> <li>● 保健省関係者の証言</li> <li>● セミナーやシンポジウムの報告書</li> <li>● 長期専門家の証言</li> <li>● BFAD 関係者の証言</li> <li>● 製薬企業関係者の証言</li> <li>● 大学薬学部関係者の証言</li> <li>● 保健省組織図最新版</li> <li>● 保健省関係者の証言</li> <li>● BFAD 関係者の証言</li> </ul>	<ul style="list-style-type: none"> <li>● 資料レビュー</li> <li>● BFAD 関係者への聞き取り</li> <li>● 資料レビュー</li> <li>● BFAD 関係者への聞き取り</li> <li>● 保健省関係者への聞き取り</li> <li>● 資料レビュー</li> <li>● BFAD 関係者への聞き取り</li> <li>● 製薬企業関係者への聞き取り</li> <li>● 大学薬学部関係者への聞き取り</li> <li>● 資料レビュー</li> <li>● BFAD 関係者への聞き取り</li> <li>● 保健省関係者への聞き取り</li> </ul>
	<p>通則・総則、試験法などの項目を作成する過程を阻害・促進する要因はあったか</p> <p>薬局方を省令で公布する過程を阻害・促進する要因はあったか</p> <p>薬局方第1版を広く知らしめる活動を阻害・促進する要因はあったか</p> <p>BFAD 内に薬局方部門を設立する過程を阻害・促進する要因はあったか</p>				
インパクト	上位目標は達成されるか	聞き取り調査による定性的評価	既に問題が発見された市場の医薬品例	<ul style="list-style-type: none"> <li>● BFAD 関係者への聞き取り</li> <li>● 製薬企業関係者への聞き取り</li> </ul>	
	上位目標達成の貢献・阻害要因はあるか	—	上位目標達成の貢献・阻害要因	<ul style="list-style-type: none"> <li>● BFAD 関係者への聞き取り</li> <li>● 製薬企業関係者への聞き取り</li> </ul>	
	プロジェクトによる望ましい・望ましくない、予想された・予想されない波及効果はあるか	保健省の政策面への影響はあるか	保健省の政策の変化	<ul style="list-style-type: none"> <li>● 保健省の政策文書</li> <li>● 保健省関係者への聞き取り</li> </ul>	
		医薬品の価格など、市場への影響はあるか	—	<ul style="list-style-type: none"> <li>● BFAD 関係者への聞き取り</li> <li>● BFAD 関係者への聞き取り</li> <li>● 製薬企業関係者への聞き取り</li> </ul>	
	その他の影響はあるか	—	—	<ul style="list-style-type: none"> <li>● 資料レビュー</li> <li>● BFAD 関係者への聞き取り</li> <li>● 製薬企業関係者への聞き取り</li> <li>● 大学関係者への聞き取り</li> </ul>	



自立発展性	プロジェクトの効果を持続させるための組織能力は十分か	薬局方委員会 (PPO) が今後も組織として機能するための制度・法は確立されているか 審議会は今後も継続して (年 1~2 回) 開催されるか TWG での作業委員会は今後も継続して開催されるか BFAD 内で薬局方の改訂作業を主管する部門は設立されるか	-	関連制度・法の文書 ● 今後の計画書、もしくは具体的な日程・内容案 ● 今後の計画書、もしくは具体的な日程・内容案 ● BFAD の新組織図案 ● 組織改変に関する保健省との協議内容	資料レビュ ● 資料レビュ ● BFAD 関係者への聞き取り ● 資料レビュ ● BFAD 関係者への聞き取り ● 資料レビュ ● BFAD 関係者への聞き取り ● BFAD 関係者への聞き取り ● 保健省関係者への聞き取り
プロジェクトの効果を持続させるための技術面は十分か	TWG I, II のメンバーがバリデーション試験を実施し、医薬品各条を改定するための十分な技術を身につけているか TWG III のメンバーが通則、総則、試験法などの項目を見直し、改定するための十分な技術を身につけているか 供与機材のメンテナンスや修理の体制は十分か	聞き取り調査による定性的な評価	● 長期専門家の証言 ● カウンタートパートの証言	● BFAD 関係者への聞き取り	
プロジェクトの効果を持続させるための財政面での支援は確保されるか	保健省の薬局方部門への予算割当ては十分か、今後も継続されるか	聞き取り調査による定性的な評価	● 長期専門家の証言 ● カウンタートパートの証言 ● 保健省予算関連資料 ● 保健省関係者の見解	● BFAD 関係者への聞き取り ● 資料レビュ ● 保健省関係者への聞き取り ● BFAD 関係者への聞き取り	
プロジェクトの自立発展性に影響を及ぼすその他の要因はあるか	-	-	-	● BFAD 関係者への聞き取り ● 保健省関係者への聞き取り	

6. 投入実績の詳細

別添6: 投入実績の詳細

I. 日本側

(1) 日本人専門家の投入

氏名	派遣開始	派遣終了	指導科目	区分	2002			2003			2004			2005				
					4	7	10	1	4	7	10	1	4	7	10	1	4	7
石橋 無味雄	2002.4.19	2005.4.22 (予定)	薬局方制定	長期														
坂本 知昭	2002.8.8	2002.9.21	薬局方 (化学医薬品各条)	短期		■												
中根 孝久	2002.10.1	2002.11.29	薬局方 (生薬医薬品各条)	短期		■												
瀬戸 隆子	2003.1.24	2003.3.1	薬局方 (生薬医薬品各条)	短期			■											
佐竹 元吉	2003.2.7	2003.2.15	生薬規格	短期			■											
坂本 知昭	2003.8.21	2003.9.2	化学医薬品各条の制定指導	短期				■										
濱田 彰	2003.8.7	2003.8.24	薬局方の公布体制の構築	短期				■										
佐竹 元吉	2004.3.25	2004.3.28	生薬医薬品各条の制定指導	短期					■									
(未定)	2005.3 (予定)	2005.3	シンポジウム講師 (行政)	短期														
(未定)	2005.3 (予定)	2005.3	シンポジウム講師 (生薬)	短期														
(未定)	2005.3 (予定)	2005.3	シンポジウム講師 (総合)	短期														

(2) カウンターパート本邦研修

氏名	開始	終了	研修コース名	性別	実施日数	所属先	2002			2003			2004			2005		
							4	7	10	1	4	7	10	1	4	7	10	1
1 RIMANDO Annie Policarpio	2002.9.26	2003.3.21	薬局方制定手法 (化学医薬品分野)	女	177	Food and Drug Regulation Officer II, Bureau of Food and Drugs			■									
2 Cherry Maharajahma Ditas Villarroja ALLIM	2003.1.28	2003.8.2	薬局方制定手法 (薬品各条制定 及び関連する科 学技術)	女	187	Food&Drug Regulation Officer II/Bureau of Food and Drugs(94-)				■								

	氏名	開始	終了	研修コース名	性別	実施 日数	所属先	2002			2003			2004			2005
								4	7	10	1	4	7	10	1	4	7
3	Luz Navarro PAGARAN	2003.3.10	2003.9.6	薬局方の制定方 法	女	181	Food and Drug Regulation Officer II/Bureau of Food and Drugs (1994-)										
4	SANTIAGO Maria Lourdes Caballero	2003.3.18	2003.4.25	個別一般薬局方 制定方法	女	39	Food&Drug Regulation Officer IV/Bureau of Food and Drugs('00-)										
5	MAGO Maria Evelyn Villalon	2003.5.27	2003.11.29	生薬医薬品各条 の制定	女	187	Food Drug Regulation Officer II/Bureau of Food and Drugs, Dept. of Health('00-)										
6	MANGMANG Nida Alfaro	2003.5.27	2003.11.29	一般試験法の制 定	女	187	Food&Drug Regulation Officer III, GMP Inspector/Bureau of Food and Drugs										
7	OCHEDA Shemaine Ocampo	2003.6.3	2003.12.6	化学医薬品各条 の制定	女	187	Food-Drug Regulation Officer II/Bureau of Food and Drugs('99-)										
8	MENANO Gloria Lopez	2004.6.15	2004.12.11	化学医薬品・生 薬医薬品各条の 制定	女	180	Pharmacist IV/Bureau of Food and Drugs('04-)										
9	SARAU Josephine Kwan	2004.8.1	2004.8.26	薬局方の制定・ 公布 (Laboratory)	女	26	Food-Drug Regulation Officer V/Bureau of Food and Drugs('88-)										
10	ALBA Ofelia Marcos	2004.9.20	2004.10.15	薬局方の制定・ 公布 (Administration)	女	26	Chief of Regulation Division II/Bureau of Food and Drugs('02-)										

(3) 機材供与と現地業務費 (単位:千円)\*

	2002年度	2003年度	2004年度	合計
供与機材**	25,288	0	0	25,288
携行機材***	17,068	14,707	6,690	38,466
現地業務費****	11,500	10,310	21,421	43,231
合計	53,856	25,017	28,111	106,985

\* 日本の会計年度 (4月~3月) を基準とした。

\*\* 供与機材については、各年次に承認された額を記載した。

\*\*\* 携行機材は、年次ごとに据付された機材の合計額を記載した。そのため、年次ごとの申請額とは必ずしも一致しない。携行機材一覧を以下に示した。

\*\*\*\* 現地業務費は、2002年度と2003年度は実際の支出額を、2004年度は承認された額を記載した。

供与機材一覧

	機材名	数量	調達区分	金額 (千円)
1.	溶出試験器	1	現地調達	1,745
2.	分光光度計用データ処理装置	2	現地調達	350
3.	高速液体クロマトグラフ	1	現地調達	3,583
4.	高速液体クロマトグラフ用カラムオープン	1	現地調達	800
5.	示差走査熱量測定装置	1	現地調達	8,217
6.	フーリエ変換赤外分光光度計用付属装置一式	1	現地調達	1,969
7.	セミクロ天秤	1	現地調達	405
8.	ビデオスター (カマグ社製) の解析装置	1	現地調達	1,000
9.	グローボックス	1	現地調達	120
10.	蒸留水製造装置	1	現地調達	388
11.	水流ポンプ (ロータリーエバポレーター用)	1	現地調達	61
12.	簡易型ドラフト	2	現地調達	925
13.	シェーカー (Shaker Labin: Model 4625-1)	1	現地調達	198
14.	マグネティックスタラー	3	現地調達	143
15.	電気炉	1	現地調達	500
16.	TLC シェンバー (20x20) double through	1	現地調達	72
17.	ロータリーマイクロトーム	1	現地調達	3,098
18.	マグネティックスタラー	1	現地調達	230
19.	卓上型 (小型) 超音波洗浄機	1	現地調達	75
20.	顕微鏡用接眼及びステージマイクロメーター	1	現地調達	63
21.	標準物質とする試薬	約 40 品	現地調達	1,346
	合計			25,288

携行機材一覧

据付日	機材名	金額 (フィリピンペソ)	金額 (日本円)	金額* (日本円相当額)
2002.9.19	Yamato Electro Freeze		413,000	413,000
2002.9.19	IBM Laptop Computer			不明**
2002.9.19	HP PSC 750 Printer		34,500	34,500
2002.9.30	Drawing Equipment		297,090	297,090
2002.9.30	Lightviewer 7000 PRO		25,450	25,450
2002.10.10	Carrier Aircondition Unit, 2HP, 1958A	21,475		49,981
2003.1.8	Series 200 Peltier Column Oven (Attached to Perkin Elmer HPLC with UV/VIS Detector delivered on 21 November 2000)	350,000		814,588
2003.1.24	Sartorius CP225D Analytical Balance			不明**
2003.1.24	Dell Laptop, Model PP01X with HP Deskjet 3420 printer (originally for Sartorius CP225D Analytical Balance)		378,500	378,500

2003.1.24	Dell Computer Workstation for the Project/Technical Secretary		295,000	295,000
2003.1.29	Mettler Toledo AG285 Analytical Balance	170,863		397,666
2003.2.4	Computer Workstation, IBM for UV-Visible Spectrophotometer	66,500		154,772
2003.2.4	Computer Workstation, IBM for UV-Visible Spectrophotometer	66,500		154,772
2003.2.5	Micrometer Eyepiece (Attached to Eurome XFB Microscope delivered 22 August 2001)	24,900		57,952
2003.2.18	Schott Water Distilling Apparatus	141,600		329,559
2003.3.3	Buchi Water Jet Pump, Part No. 23349	24,050		55,974
2003.3.6	Precisa BJ2100D Top Loading Balance, SN: P688244	37,268		86,738
2003.3.12	Precisa BJ 2100D Top Loading Balance, SN: 93608			不明**
2003.3.13	Universal ATR Sampling (Attached to Perkin Elmer Spectrum 1 delivered on 26 October 2001)	528,330		1,229,633
2003.3.13	Oasis D125 Frost-Free Dehumidifier, 100% CFC Free	51,994		121,010
2003.3.13	Perkin Elmer Pyris 6 TGA-DSC with Computer Workstation	2,927,052		6,812,405
2003.3.28	Shimadzu High Performance Liquid Chromatography with UV-VIS Detector	1,504,000		3,500,401
2003.3.28	Shimadzu UV-Visible Spectrophotometer with Computer Workstation (Pharmaspec UV-1700)	633,766		1,475,024
2003.3.31	Naberthem Laboratory Furnace	165,000		384,020
<b>2002 年度小計</b>				<b>17,068,035</b>
2003.4.3	Videoscan Software (for Camag Reprostar 3 delivered in 24 November 2000)	540,000		1,113,525
2003.4.10	Heating Mantle 1L with Slider and Transformer		38,000	38,000
2003.4.10	Heating Mantle 1L with Slider and Transformer		38,000	38,000
2003.4.29	HM 360 Rotary Microtome, SN: 25956; Accessories: adjustable universal cassette clamp, edgerite disposable blades, disposable blade carrier, and large field magnifier	939,800		1,937,947
2003.7.1	Series 200 Autosampler, N293-0100, with autosample flush bottle (Attached to Perkin Elmer HPLC with UV/VIS Detector delivered on 21 November 2000)	772,358		1,592,667
2003.8.18	Multiple Stirrer Magnestir, Labline 1278, Thomas Catalogue No. 0522-1320 with 1000 watt transformer	111,525		229,974
2003.8.18	Corning Hot Plates Stirrer, Model: PC-210, Lab Stirrer, S/N: 250103163736, Thomas Cat. No. 8613-H80, with 250 watt transformer	20,190		41,633
2003.8.18	Corning Hot Plates Stirrer, Model: PC-210, Lab Stirrer, S/N: 250103163680 (Thomas Cat. No. 8613-H80, with 250 watt transformer)	20,190		41,633
2003.8.18	Corning Hot Plates Stirrer, Model: PC-210, Lab Stirrer, S/N: _____ (Thomas Cat. No. 8613-H80, with 250 watt transformer)	20,190		41,633

2003.8.18	Ultrasonic Cleaner Bath, Sonicator, Branson, Model: 2510, Thomas Cat. No. 2892-G50, Accessories: Insert tray perforated, Cat No. 2892-G60 and Basket, wire mesh, Cat No. 2892-G65 with 750 watts transformer	58,616		120,871
2003.8.28	Neytech Ultrasonic Cleaner with Panther Transformer	81,000		167,029
2003.8.28	Neytech Ultrasonic Cleaner with Panther Transformer	81,000		167,029
2003.8.28	Neytech Ultrasonic Cleaner with Panther Transformer	81,000		167,029
2003.9.17	Precisa HA 300 Moisture Balance (SN:76369) with Precisa Model 310M Top Loading Balance (SN:76366)	177,929		366,904
2003.10.8	Domnick Hunter UHP ZN1001 Nitrogen Gas Generator, SN: 0300572	568,000		1,171,264
2003.11.13	Schott CG842 pH Meter with Z851 power supply / adapter SN: 99232782 / 0321	54,086		111,530
2003.11.13	Schott CG842 pH Meter with Z851 power supply / adapter SN: 99232780 / 0321	54,086		111,530
2003.11.13	Schott CG842 pH Meter with Z851 power supply / adapter SN: 99232777 / 0321	54,086		111,530
2003.11.13	Schott CG842 pH Meter with Z851 power supply / adapter SN: 99232781 / 0321	54,086		111,530
2003.12.1	Welch Rietschle Thomas 2010 Dry Vacuum Pump	130,400		268,896
2003.12.1	Economic Analytical Mill with Beater plus extra cutting blades and beater	92,400		190,537
2003.12.1	Cole Parmer Jiffy Jack	10,700		22,064
2003.4.8	Fumehood (Esco Smart Control)	140,000		288,692
2003.4.8	Fumehood (Esco Smart Control)	140,000		288,692
2004.1.15	Heavy Duty Carts with Guard Rails (2 layer shelves with 6" swivel caster wheel, 300kg loading capacity)	44,800		92,381
2004.3.12	Fluorescence Detector RF-10AXL (Attached to Shimadzu HPLC with UV-VIS Detector delivered on 28 March 2003)	1,304,400		2,689,783
2004.3.1	Kelvinator Blood Bank Refrigerator	520,560		1,073,439
2004.3.31	Millipore Steritest Compact Pump System and Consumables	1,024,000		2,111,574
<b>2003 年度小計</b>				<b>14,707,316</b>
2004.5.24	Cole Parmer A-33900-45 Muffle Furnace	380,000		738,285
2004.5.31	AccuSizer 780/SIS Syringe Injection Sampler with Computer Workstation	2,980,000		5,789,710
2004.8.10	Daikin Air Conditioning Unit 3.0HP Ceiling Cassette Type	83,636		162,493
<b>2004 年度小計</b>				<b>6,690,488</b>
<b>合計</b>				<b>3,8465,839</b>

\* 現地で調達した機材については、年次ごとの平均換算レートを用いて日本円相当額に換算した。平均換算レートは、2002年度が0.4297ペソ/円、2003年度が0.4849ペソ/円、2004年度が0.5147ペソ/円。

\*\* 金額が不明な分については、合計額から除いた。

## II. フィリピン側

### (1) 業務費・人材配置\*

	2002年度	2003年度	2004年度
業務費（単位：千ペソ）**	2,500	1,500	1,500
人材配置（専従職員相当人数）***	19.7人	20.3人	20.6人

\* フィリピンの会計年度（1月～12月）を基準とした。

\*\* 業務費は承認された額を記載した。

\*\*\* カウンターパート一覧を以下に示した。

#### カウンターパート一覧(マネジメントスタッフ;2004年4月15日現在)

氏名		個人情報	
1.	Ms. Maria Lourdes C. Santiago	ニックネーム：	Lulu
		役職：	Food-Drug Regulation Officer IV
		経験：	Drug Analysis, Evaluation, and Registration
		学歴：	BS Pharmacy, University of Santo Tomas (1982-1987)
		プロジェクトでの役割：	Project Manager, DOH Pharmacopeial Organization Officer-in-Charge, Philippine Pharmacopeia Project
		BFADでの役割：	Officer-in-Charge, Philippine Pharmacopeia Project Supervisor, Antibiotic Section, Laboratory Services Division
2.	Ms. Josephine K. Sarau	ニックネーム：	Jo
		役職：	Food-Drug Regulation Officer V
		経験：	Supervisor – Physico-Chemical Section, BFAD, Laboratory Services Division; Senior Clinical Pharmacist (1984-1988), Makati Medical Center
		学歴：	MS Pharmacy, University of Santo Tomas; BS Pharmacy, University of Santo Tomas (1978-1983)
		プロジェクトでの役割：	Assistant Project Manager, DOH Pharmacopeial Organization
		BFADでの役割：	Chief, Product Services Division
3.	Ms. Therese Irynne R. Gonzales	ニックネーム：	Irynne
		役職：	Food-Drug Regulation Officer III
		経験：	Drug Analysis, Evaluation, and Registration
		学歴：	BS Industrial Pharmacy, University of the Philippines Manila (1981-1987)
		プロジェクトでの役割：	Supervisor, Philippine Pharmacopeia Project
		BFADでの役割：	Operations Manager, Office of the Director

#### カウンターパート一覧(その他のスタッフ;2004年4月15日現在)

	氏名	所属先	役職	プロジェクトへの関与
1	Ms. Alma A. Aguinaldo	Bureau of Food and Drugs	Food-Drug Regulation Officer III	必要に応じて
2	Ms. Ofelia M. Alba	Bureau of Food and Drugs	Food-Drug Regulation Officer V	パートタイム
3	Ms. Cherry V. Alim	Bureau of Food and Drugs	Food-Drug Regulation Officer II	フルタイム
4	Ms. Jaydee S. Andaya	Bureau of Food and Drugs	Food-Drug Regulation Officer III	必要に応じて
5	Ms. Helen A. Balde	Bureau of Food and Drugs	Food-Drug Regulation Officer III	パートタイム
6	Ms. Jocelyn E. Balderrama	Bureau of Food and Drugs	Food-Drug Regulation Officer III	フルタイム
7	Ms. Zenaida T. Baumann	Bureau of Food and Drugs	Food-Drug Regulation Officer IV	パートタイム
8	Ms. Girlie D. Bautista	Bureau of Food and Drugs	Food-Drug Regulation Officer III	パートタイム
9	Ms. Pia Rose A. Belarmino	Bureau of Food and Drugs	Food-Drug Regulation Officer II	必要に応じて
10	Ms. Haydee R. Boton	Bureau of Food and Drugs	Food-Drug Regulation Officer III	必要に応じて
11	Ms. Susana D. Calambro	Bureau of Food and Drugs	Food-Drug Regulation Officer II	パートタイム
12	Ms. Jesusa Joyce N. Cirunay	Bureau of Food and Drugs	Food-Drug Regulation Officer III	パートタイム

13	Ms. Rosario M. Dela Cruz	Bureau of Food and Drugs	Food-Drug Regulation Officer II	フルタイム
14	Ms. Caroline Imelda B. Fujishiro	Bureau of Food and Drugs	Food-Drug Regulation Officer III	フルタイム
15	Ms. Florlita Ma. H. Gabuna	Bureau of Food and Drugs	Food-Drug Regulation Officer III	パートタイム
16	Atty. Ireneo M. Galicia	Bureau of Food and Drugs	Attorney	必要に応じて
17	Prof. Leticia-Barbara B. Gutierrez, MS	Bureau of Food and Drugs	Director	審議会委員長
18	Ms. Lucila R. Javier	Bureau of Food and Drugs	Food-Drug Regulation Officer II	フルタイム
19	Ms. Virginia Francia C. Laboy	Bureau of Food and Drugs	Food-Drug Regulation Officer III	パートタイム
20	Ms. Nazarita T. Lanuza	Bureau of Food and Drugs	Food-Drug Regulation Officer V	パートタイム
21	Ms. Maria Evelyn V. Mago	Bureau of Food and Drugs	Food-Drug Regulation Officer II	フルタイム
22	Mr. Marvin C. Malonzo	Bureau of Food and Drugs	Food-Drug Regulation Officer II	フルタイム
23	Ms. Rhoda Laine D. Manaloto	Bureau of Food and Drugs	Food-Drug Regulation Officer IV	必要に応じて
24	Ms. Nida A. Mangmang	Bureau of Food and Drugs	Food-Drug Regulation Officer III	フルタイム
25	Ms. Luzviminda O. Marquez	Department of Health	Consultant, National Drug Policy Program	必要に応じて
26	Ms. Rosario E. Martin	Bureau of Food and Drugs	Food-Drug Regulation Officer IV	パートタイム
27	Ms. Gloria L. Meñano	Bureau of Food and Drugs	Food-Drug Regulation Officer II	パートタイム
28	Ms. Juvy Pilar M. Montillano	Bureau of Food and Drugs	Food-Drug Regulation Officer III	パートタイム
29	Ms. Florita D. Moraleja	Bureau of Food and Drugs	Attorney II	パートタイム
30	Ms. Regina S. Obligacion	Bureau of Food and Drugs	Food-Drug Regulation Officer III	必要に応じて
31	Ms. Shemaine O. Ocheda	Bureau of Food and Drugs	Food-Drug Regulation Officer II	パートタイム
32	Ms. Celia L. Ong	Bureau of Food and Drugs	Food-Drug Regulation Officer III	必要に応じて
33	Ms. Rizalina A. Opinion	Bureau of Food and Drugs	Food-Drug Regulation Officer V	退職
34	Ms. Jennifer M. Oribello	Bureau of Food and Drugs	Food-Drug Regulation Officer II	フルタイム
35	Engr. Luz N. Pagaran	Bureau of Food and Drugs	Food-Drug Regulation Officer II	フルタイム
36	Ms. Liza S. Pajarillo	Bureau of Food and Drugs	Food-Drug Regulation Officer II	必要に応じて
37	Atty. Emil Polig, Jr.	Bureau of Food and Drugs	Attorney	必要に応じて
38	Ms. Lanette Lee A. Querubin	Bureau of Food and Drugs	Food-Drug Regulation Officer II	パートタイム
39	Ms. Annie P. Rimando	Bureau of Food and Drugs	Food-Drug Regulation Officer III	フルタイム
40	Ms. Teresita D. Romero	Bureau of Food and Drugs	Food-Drug Regulation Officer III	必要に応じて
41	Ms. Emma Concepcion M. Santero	Bureau of Food and Drugs	Food-Drug Regulation Officer IV	フルタイム(休職中)
42	Mrs. Eliza Garcia-Sison	Bureau of Food and Drugs	Food-Drug Regulation Officer II	必要に応じて
43	Mr. Loreto M. Urciada	Bureau of Food and Drugs	Utility Worker I	フルタイム
44	Ms. Ma. Theresa Pia C. Yap	Bureau of Food and Drugs	Food-Drug Regulation Officer III	必要に応じて
45	Ms. Yolanda O. Zurita	Bureau of Food and Drugs	Food-Drug Regulation Officer II	フルタイム

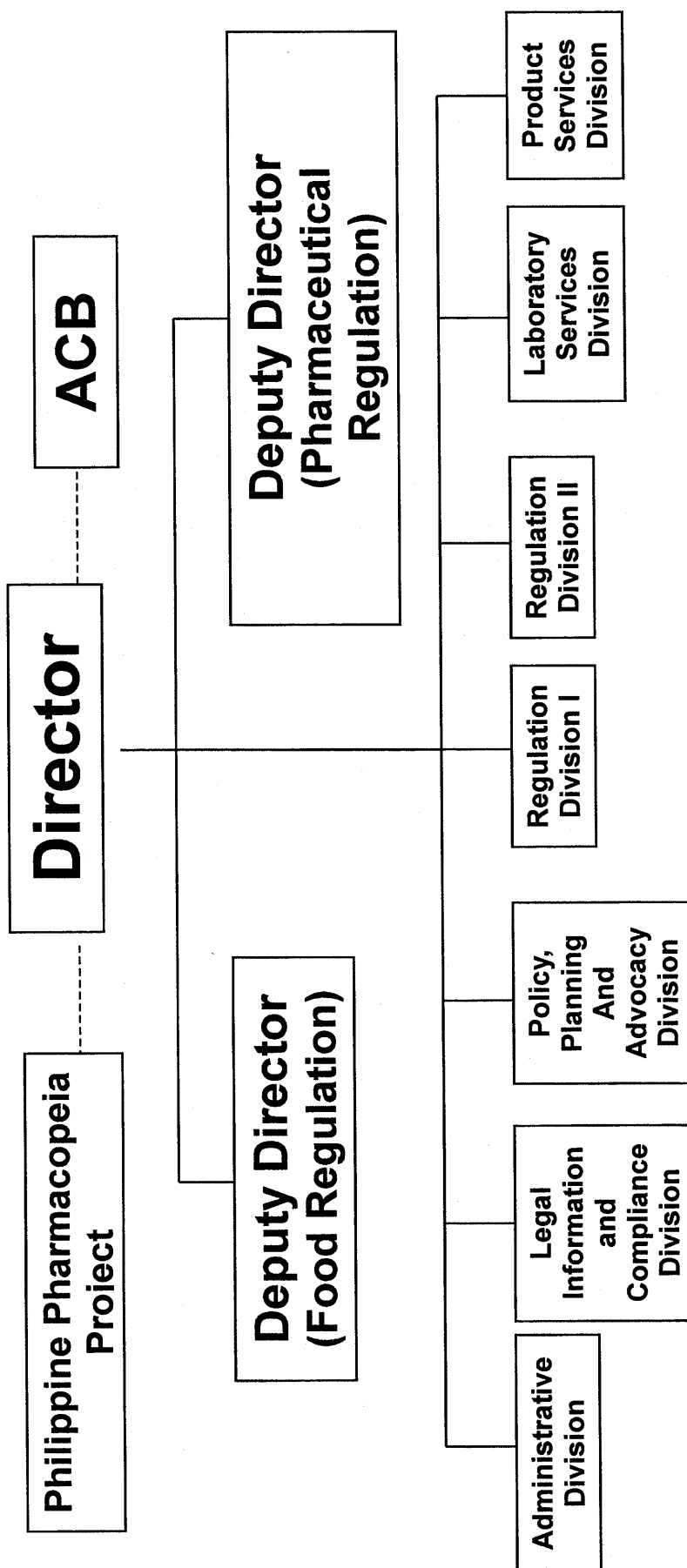
## (2) 機材と施設

分類	品目
機材	<ol style="list-style-type: none"> <li>1. ガスクロマトグラフ (2台)</li> <li>2. 高速液体クロマトグラフ (3台)</li> <li>3. 紫外・可視分光光度計</li> <li>4. 原子吸光光度計</li> <li>5. 滅菌試験システム</li> <li>6. コロニーカウンター</li> <li>7. ろ過装置</li> <li>8. 加熱炉 (2台)</li> <li>9. 乾燥機 (2台)</li> </ol>
施設	<ol style="list-style-type: none"> <li>1. 事務所機器 (机、コンピュータ、いす、棚、電話; 214号室)</li> <li>2. 試験室 (4室; Laboratory Rooms (4 rooms; 研究、血液、解剖、顕微鏡)</li> <li>3. 倉庫 (暗室1)</li> <li>4. 会議室 (200号室)</li> <li>5. 機器室 (5室; 電子顕微鏡室、赤外線室、顕微鏡室、機器室2、温室)</li> </ol>



7. BFAD 組織図

7-1 BFAD 組織図 (現行)

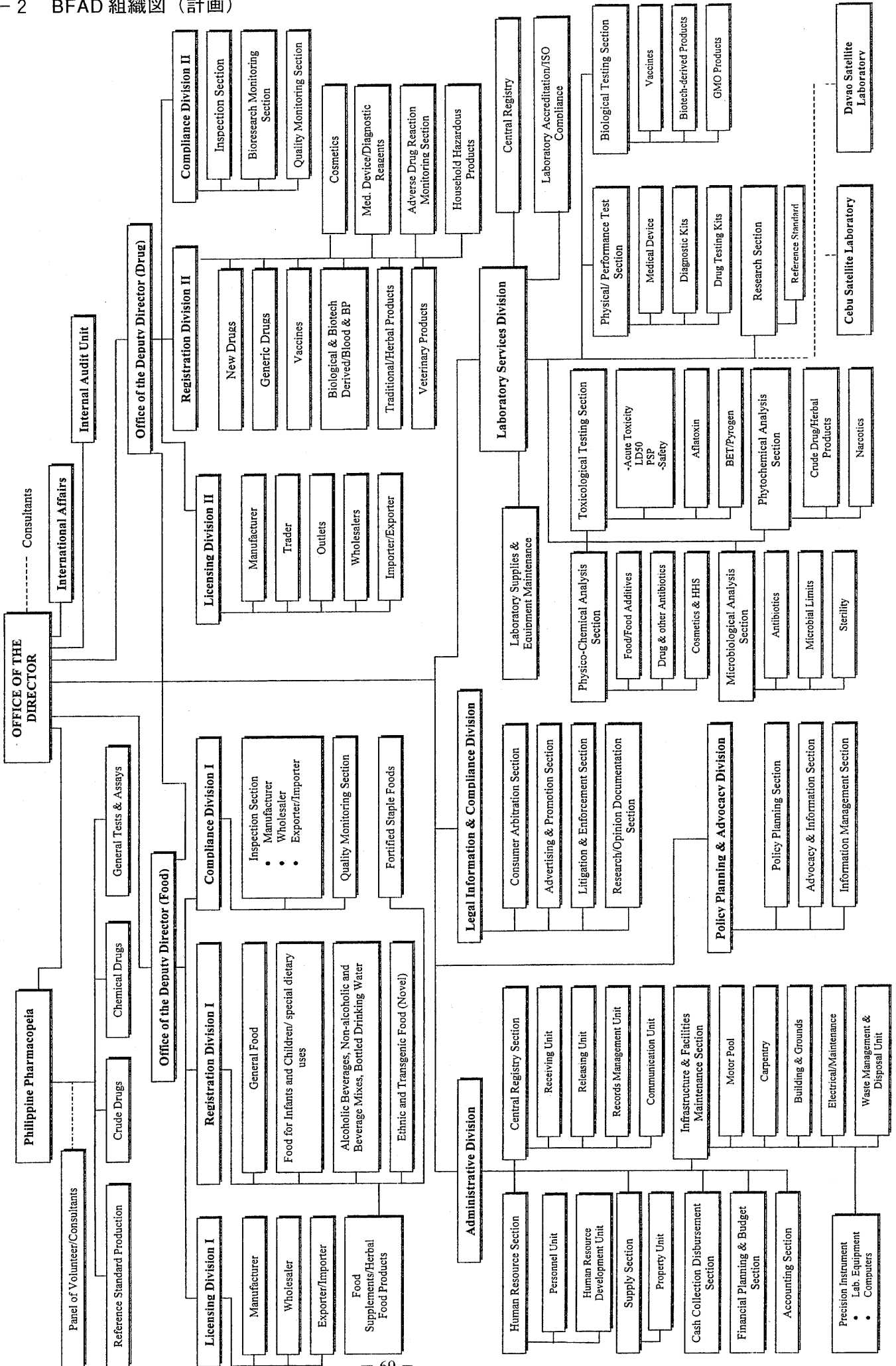


別添 7-1: BFAD 組織図 (現行)

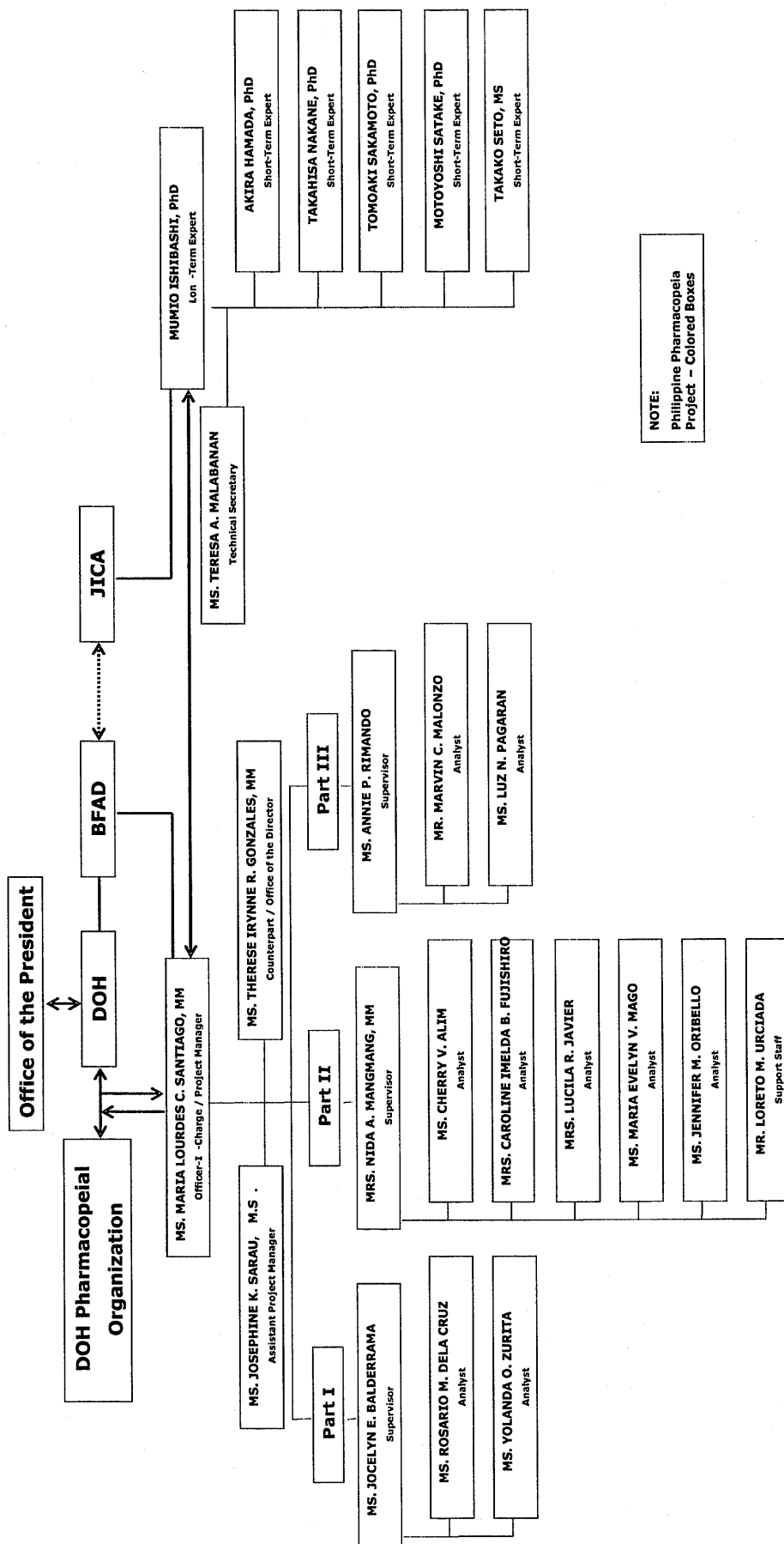
**DRAFT ONLY**  
AS OF 24 SEPT. 2003

**BUREAU OF FOOD AND DRUGS**  
PROPOSED ORGANIZATIONAL STRUCTURE (Per E.O 102)

別添 7-2: BFAD 組織圖 (計畫)



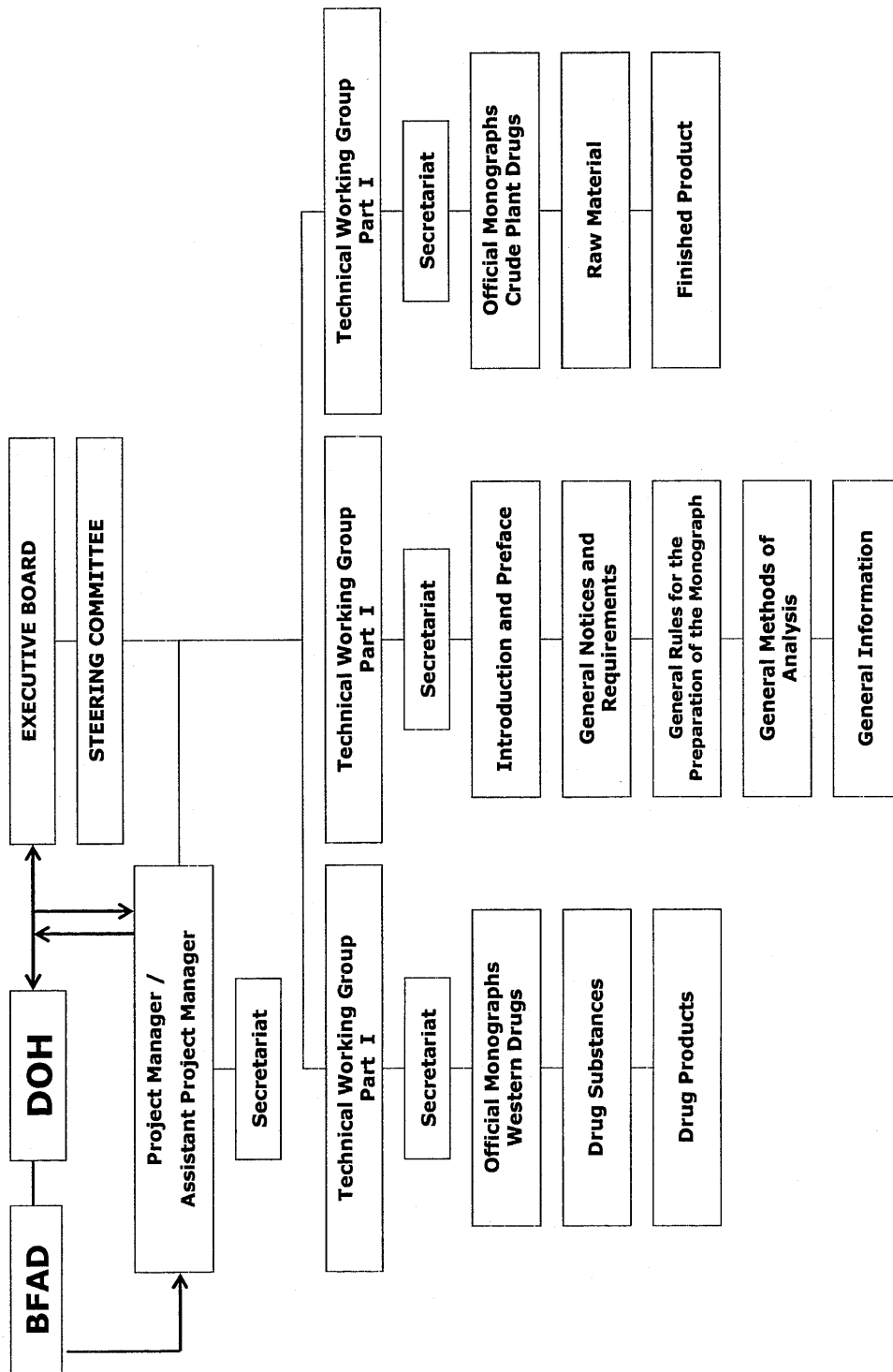
別添 8: フィリピン薬局方プロジェクト組織図



NOTE:  
Philippine Pharmacopoeia  
Project - Colored Boxes

9. フィリピン薬局方委員会組織図

別添 9: フィリピン薬局方委員会組織図



10. フィリピン薬局方委員会設立の公式文書

**The DOH Pharmacopeial Organization**



Republic of the Philippines  
Department of Health  
OFFICE OF THE SECRETARY

448-3  
SAN LAZARO COMPOUND  
RIZAL AVENUE, STA. CRUZ  
MANILA, PHILIPPINES  
TEL. NO. 711-60-80

May 26, 1999

DEPARTMENT ORDER  
No. 216-F, s. 1999

Subject: Creation of DOH Pharmacopeial Organization for the Preparation and Publication of the Philippine Pharmacopeia

In order to effectively implement the Philippine Pharmacopeia Project of the Department of Health, the Bureau of Food and Drugs, in collaboration with various government, non-government organizations and the Government of Japan under a Technical Cooperation Scheme, a DOH Pharmacopeial Organization is hereby created with the following goals and objectives:

I. GOAL

To prepare and publish the Philippine Pharmacopeia which shall serve as and be utilized as the official national reference book of standards for the determination of the identity, purity, efficacy and quality of pharmaceutical substances and products including Philippine medicinal plant materials and natural products.

II. OBJECTIVES

1. To establish standards of purity, efficacy and quality for pharmaceutical substances and products that are present in the Philippine market and to develop monographs of such standards
2. To establish standards of identity, purity and quality for Philippine medicinal plant materials and natural products and to develop monographs of such standards
3. To develop appropriate tests and analytical procedures for the determination of compliance to the established standards
4. To publish a Philippine Pharmacopeia, which shall contain the monographs, analytical procedures, specifications and requirements of the standards.

**Certified True Copy:**

*Lamberta G. Manuel*  
**LAMBERTA G. MANUEL**  
OIC, Records Section  
DOH - Manila

6/4/99

### III. ORGANIZATIONAL SET-UP

The DOH Pharmacopeial Organization shall be composed of an Executive Board, a Steering Committee, and Technical Working Groups (TWG) for each of the relevant areas of standardization work for the Pharmacopeia. The work of the TWGs shall be supervised by the Steering Committee where the group leaders of each of the TWG's shall be members. Policy direction for the organization will be provided by the Pharmacopeial Board.

#### Terms of References:


##### Executive Board

1. Provide overall policy direction
2. Endorse the work plan of the organization and its budgetary requirements to the Secretary of Health
3. Establish funding resources
4. Review and approve the recommendations of the TWG's
5. Recommend membership to the TWG's and create ad-hoc task forces as the need arises
6. Ensure the continued development and revisions of the Pharmacopeia

##### Steering Committee

1. Supervise and support the work of the TWG's
2. Review issues and recommend activities to be undertaken by the TWG's
3. Review and report work plans and budgetary requirements of the TWG's to the Executive Board
4. Monitor implementation of work plans and submission of reports of the TWG's
5. Recommend the composition of the TWG's
6. Coordinate activities of the TWG's

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DOH - Manila

6/4/59


### Technical Working Group

1. Formulate work plans and conduct activities towards the development of the Philippine Pharmacopeia
2. Formulate guidelines in the selection of standards, format and drafting of the Philippine Pharmacopeia
3. Submit project, training and/or research proposals in accordance with the proposed work plans
4. Coordinate research activities in order to develop standards of identity, purity and quality for Pharmaceutical substances and products, including those for Philippine medicinal plants and natural products
5. Provide scientific and technical support in the development and completion of the Philippine Pharmacopeia
6. Submit to the Executive Board reports of accomplishments and other relevant documents on a regular basis.

### Secretariat

1. Provide assistance to the TWG's in the conduct of activities toward the development of the Philippine Pharmacopeia
2. Ensure the timely arrival and dissemination of document to relevant members of the Organization
3. Act as Secretariat to the Executive Board
4. Establish a Philippine Pharmacopeial information system that will ensure timely notification of members regarding relevant matters
5. Prepare and consolidate budget requirements of the Organization in coordination with the TWG's
6. Prepare and consolidate minutes of meetings held by the Executive Board, Steering Committee and the different TWG's
7. Conduct research activities in accordance with the needs of the different TWG's.

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OIC, Records Section  
GDH - Manila

6/4/99



The following shall be the members of the DOH Pharmacopeial Organization:

**Executive Board**

- |                            |   |  |
|----------------------------|---|--|
| 1. Dr. William D. Torres   | - | Bureau of Food and Drugs                               |
| 2. Dr. Quintin L. Kintanar | - | DOH / DOST   |
| 3. Dr. Conrado Dayrit      | - | DOST / National Academy of Science and Technology      |
| 4. Dr. Pacita L. Zara      | - | Philippine Council for Health Research and Development |
| 5. Dr. Natividad de Castro | - | Philippine Pharmaceutical Association                  |

**Steering Committee**

- |                            |   |  |
|----------------------------|---|--|
| 1. Atty. Froilan Bagabaldo | - | UP College of Pharmacy                               |
| 2. Dr. Magdalena Cantoria  | - | DOST / NAST, UP Pharmacy                             |
| 3. Prof. Ludivina de Padua | - | UPLB; Institute of Biological Sciences               |
| 4. Ms. Estelita N. Garcia  | - | Retired Industrial Pharmacist                        |
| 5. Dr. Cleotilde How       | - | UP College of Medicine, Dept. of Pharmacology        |
| 6. Dr. Alfonso Lagaya      | - | DOH Traditional Medicine Unit                        |
| 7. Dr. Norma Lerma         | - | UST College of Pharmacy                              |
| 8. Dr. Abraham Pascual     | - | Pascual Laboratories, Inc. (Pharmaceutical Industry) |
| 9. Dr. Benigno Pecson      | - | United Laboratories Inc.                             |

**Technical Working Groups**

**A. TWG on Book I**

- |                               |   |                             |
|-------------------------------|---|-----------------------------|
| 1. Ms. Estelita N. Garcia     | - | BFAD                        |
| 2. Ms. Ofelia M. Alba         | - | PAPPI                       |
| 3. Ms. Marian Andaluz         | - | Ateneo de Manila University |
| 4. Dr. Modesto Chua           | - | United Laboratories Inc.    |
| 5. Ms. Lilia Dizon            | - | BFAD                        |
| 6. Ms. Therese Iryne Gonzalez | - | United Laboratories Inc.    |
| 7. Dr. Cecilia Isaac          | - | UP Dept. of Pharmacology    |
| 8. Dr. Cleotilde How          | - | United Laboratories Inc.    |
| 9. Dr. Pilar Lim-Navarro      | - | PAPPI                       |
| 10. Ms. Edelweiss Mallari     | - | BFAD                        |
| 11. Ms. Luzviminda Marquez    | - | BFAD                        |

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**LAMBERTA G. MANUEL**

**OIC, Records Section**

**DOH - Manila**

- |                              |   |                                   |
|------------------------------|---|-----------------------------------|
| 12. Ms. Rizalina Opinion     | - | BFAD                              |
| 13. Dr. Estrella Paje-Villar | - | Chairman, National Drug Committee |
| 14. Ms. Ma. Lourdes Santiago | - | BFAD, NDP Q-Pillar Manager        |

**B. TWG on Book II**

- |                                     |   |  |
|-------------------------------------|---|--|
| 1. Prof. Ludivina de Padua          | - | UPLB, Institute of Biological Science            |
| 2. Dr. Alice Aguinaldo              | - | UST Dept. of Chemistry                           |
| 3. Dr. Adoracion Aranez             | - | UP Dept. of Botany                               |
| 4. Dr. Eliseo Banaynal              | - | DOH Traditional Medicine Unit                    |
| 5. Dr. Magdalena Cantoria           | - | UP College of Pharmacy                           |
| 6. Dr. Fabian Dayrit                | - | Ateneo de Manila University                      |
| 7. Dr. Eduardo de Leon              | - | UST College of Pharmacy                          |
| 8. Dr. Francis Gomez                | - | Pascual Laboratories, Inc.                       |
| 9. Prof. Rhodora Gonzalez           | - | UST College of Pharmacy                          |
| 10. Prof. Leticia-Barbara Gutierrez | - | UP College of Pharmacy                           |
| 11. Dr. Nelia Cortes-Maramba        | - | UP College of Medicine                           |
| 12. Prof. Gloria D. Manalo          | - | NRCP   |
| 13. Dr. Pilar Lim-Navarro           | - | United Laboratories Inc.                         |
| 14. Prof. Ernesta Quintana          | - | UP College of Agriculture, Dept. of Horticulture |
| 15. Dr. Isidro Sia                  | - | UP College of Medicine                           |
| 16. Prof. Priscilla Torres          | - | UST College of Pharmacy                          |

**C. TWG on the General Considerations**

- |                            |   |  |
|----------------------------|---|--|
| 1. Dr. Benigno Pecson      | - | United Laboratories Inc.               |
| 2. Atty. Amelia Ancog      | - | DOST Undersecretary                    |
| 3. Atty. Froilan Bagabaldo | - | UP Coll. of Pharmacy                   |
| 4. Atty. Zandra Bato       | - | BFAD                                   |
| 5. Mr. Rodrigo A. Castillo | - | BFAD                                   |
| 6. Prof. Ludivina de Padua | - | UPLB, Institute of Biological Sciences |
| 7. Atty. Lorna Filipino    | - |  |
| 8. Ms. Estelita N. Garcia  | - | United Laboratories Inc.               |
| 9. Ms. Nazarita T. Lanuza  | - | BFAD                                   |
| 10. Ms. Rosario Martin     | - | BFAD                                   |
| 11. Ms. Rosalina Nolasco   | - | Swiss Pharma Inc.                      |
| 12. Dr. Elizabeth Tan      | - | United Laboratories Inc.               |
| 13. Mr. Rey Umali          | - | Abbott Labs. Inc.                      |

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*L. Manuel*  
**LAMBERTA G. MANUEL**  
**OIC, Records Section**  
 Bldg. - Manila  
*6/4/59*

**Secretariat**

**Book I**

Ms. Alma Aquinaldo  
Ms. Florida Garcia  
Ms. Virginia F.C. Laboy  
Ms. Nida Mangmang  
Ms. Pia Rose Belarmino  
Ms. Juvy Pilar Montillano  
Ms. Liza Pajarillo  
Ms. Jocelyn Vargas

**Book II**

Ms. Cherry Alim  
Atty. Zandra Bato  
Ms. Haydee Boton  
Ms. Mercedita Cacao  
Ms. Erwina de Castro  
Ms. Lanette Lee Acoba  
Ms. Gloria Menano  
Ms. Regina Obligacion  
Ms. Jennifer Oribello  
Ms. Teresita Romero  
Ms. Theresa Pia Yap

**General Considerations**

Ms. Zenaida Baumann  
Ms. Rhoda Laine Manoloto  
Ms. Marita De Chavez  
Ms. Evangeline Pagsanhan  
Ms. Araceli Torres  
Ms. Florita Descallar

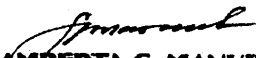
**Support Staff:**

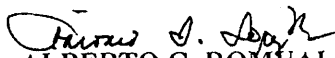
Ms. Grace Gianan

To coordinate the operations of the different TWGs and ensure the efficient and effective flow of activities, Ms. Emma Concepcion M. Santero and Ms. Josephine K. Sarau, shall act as Project Manager and Assistant Project Manager, respectively.

The maintenance and other operating expenses of the DOH Pharmacopeial Organization shall be charged against the BFAD funds and NDP funds sub-allotted to BFAD subject to the usual accounting and auditing rules and regulation.

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**LAMBERTA G. MANUEL**  
OIC, Records Section  
DOH - Manila

  
**ALBERTO G. ROMUALDEZ, JR., M.D.**  
Secretary of Health 6/3/99



Republic of the Philippines  
Department of Health  
OFFICE OF THE SECRETARY

SAN LAZARO COMPOUND  
RIZAL AVENUE, STA. CRUZ  
MANILA, PHILIPPINES  
TEL. NO. 711-80-80

November 7, 2001

DEPARTMENT ORDER  
No. 352-F, s. 2001

Subject: Amending Department Order No. 216 – F, s. 1999, Creation of the DOH Pharmacopeial Organization for the Preparation and Publication of the Philippine Pharmacopeia

In order to fully accomplish the objectives of the Philippine Pharmacopeia Project of the Department of Health, Department Order No. 216-F, s. 1999, with subject "Creation of the DOH Pharmacopeial Organization for the Preparation and Publication of the Philippine Pharmacopeia", is hereby amended to include new members and provide for its re-organization.

The DOH Pharmacopeial Organization shall have the following members:

A. Executive Board

- |                                 |   |
|---------------------------------|---|
| 1. William D. Torres, Ph.D.     | - DOH Bureau of Food and Drugs                                |
| 2. Quintin L. Kintanar, MD, PhD | - DOH /DOST National Academy of Science and Technology        |
| 3. Conrado Dayrit, MD           | - DOST / National Academy of Science and Technology           |
| 4. Pacita L. Zara, MD           | - DOST/ Philippine Council for Health Research and Technology |
| 5. Natividad de Castro, PhD     | - Philippine Pharmaceutical Association                       |

- |                           |                                  |
|---------------------------|----------------------------------|
| B. Project Manager        | - Ms. Emma Concepcion M. Santero |
| Assistant Project Manager | - Ms. Josephine K., Sarau, MSc.  |
| Technical Secretary       | - Ms. Elisa Garcia               |

Signed                       
Received in the Records  
Section on 11/20/01

### **C. Steering Committee**

1. Atty. Froilan Bagabaldo - UP College of Pharmacy
2. Dr. Magdalena Cantoria - DOST/NAST, UP College of Pharmacy
3. Prof. Ludivina S. de Padua - UPLB, Institute of Biological Sciences
4. Ms. Estelita N. Garcia - United Laboratories, Inc. (Retired)
5. Cleotilde How, MD - UP College of Medicine
6. Alfonso Lagaya, MD - Phil. Institute of Traditional and Alternative Medicine
7. Norma Lerma, PhD - UST Faculty of Pharmacy
8. Abraham Pascual, MD - Pascual Laboratories, Inc.
9. Mr. Reynaldo Umali - Euro-Med Laboratories, Inc.

### **Technical Working Groups (TWG)**

#### **A. TWG on Book I**

**Group Leader: Ms. Estelita N. Garcia**

**Asst. Group Leader: Ms. Ma. Lourdes C. Santiago**

1. Ms. Celia Algame - Wyeth Phils. Inc.
2. Ms. Marian Andaluz - Phil. Association of Pharmacists in the Pharmaceutical Industry
3. Ms. Ma. Rosario Barangan - EL Laboratories
4. Modesto Chua, PhD - Ateneo de Manila University
5. Ms. Belma del Campo - Hizon Laboratories, Inc.
6. Ms. Lilia Dizon - United Laboratories, Inc.
7. Cleotilde How, MD - UP College of Medicine
8. Cecilia Isaac, MD - United laboratories, Inc.
9. Ms. Sothie Jordan - Swiss Pharma Research Laboratories
10. Ms. Edelweiss Mallari - Phil. Association of Pharmacists in the Pharmaceutical Industry PAPPI
11. Pilar Lim-Navarro, PhD - United Laboratories Inc.
12. Marina Osi, PhD - The Boots Co., Inc.
13. Ms. Frances Evelyn Robles - Association of Drug Industries in the Phils.
14. Ms. Esther Velarde - Lloyd Laboratories, Inc.

15. Ms. Alma A. Aguinaldo	-	Bureau of Food and Drugs
16. Ms. Ofelia M. Alba	-	Bureau of Food and Drugs
17. Ms. Jaydee Andaya	-	Bureau of Food and Drugs
18. Ms. Jocelyn Balderrama	-	Bureau of Food and Drugs
19. Ms. Girlie Bautista	-	Bureau of Food and Drugs
20. Ms. Pia Rose Belarmino	-	Bureau of Food and Drugs
21. Ms. Susan Calambro	-	Bureau of Food and Drugs
22. Ms. Rosario de la Cruz	-	Bureau of Food and Drugs
23. Ms. Flor Gabuna	-	Bureau of Food and Drugs
24. Ms. Therese Irynne Gonzalez	-	Bureau of Food and Drugs
25. Ms. Virginia France Laboy	-	Bureau of Food and Drugs
26. Ms. Nida Mangmang	-	Bureau of Food and Drugs
27. Mr. Marvin Malonzo	-	Bureau of Food and Drugs
28. Ms. Luzviminda O. Marquez	-	Bureau of Food and Drugs
29. Ms. Juvy Pilar Montillano	-	Bureau of Food and Drugs
30. Ms. Rizalina Opinion	-	Bureau of Food and Drugs
31. Ms. Celia Ong	-	Bureau of Food and Drugs
32. Ms. Lisa Pajarillo	-	Bureau of Food and Drugs
33. Ms. Annie Rimando	-	Bureau of Food and Drugs
34. Ms. Jocelyn Vargas	-	Bureau of Food and Drugs
35. Ms. Yolanda Zurita	-	Bureau of Food and Drugs

#### **B. TWG on Book II**

**Group Leader: Dr. Magdalena C. Cantoria**

**Asst. Group Leader: Prof. Ludivina de Padua**

1. Alicia Aguinaldo, PhD	-	UST, Department of Chemistry
2. Adoracion Aranez, PhD	-	UP, Institute of Biology
3. Liza Asuncion, MD	-	Pascual Laboratoires, Inc.
4. Eliseo T. Banaynal Jr., MD	-	Phil. Institute of Traditional and Alternative Medicine
5. Inocencio Buot Jr., PhD	-	UPLB, Institute of Biological Sciences
6. Lourdes J. Cruz, PhD	-	University of the Philippines
7. Fabian M. Dayrit, PhD	-	Ateneo de Manila Univ.

- |     |                                   |   |  |
|-----|-----------------------------------|---|--|
| 8.  | Eduardo P de Leon, PhD            | - | UST, Department of Chemistry                               |
| 9.  | Francis Wade Gomez, MD            | - | Pascual Laboratories, Inc.                                 |
| 10. | Prof. Rhodora E. Gonzalez         | - | UST, Faculty of Pharmacy                                   |
| 11. | Dean Leticia Barbara B. Gutierrez | - | UP College of Pharmacy                                     |
| 12. | Alfonso Lagaya, MD                | - | Phil. Institute of Traditional and<br>Alternative Medicine |
| 13. | Norma V. Lerma, PhD               | - | UST, Faculty of Pharmacy                                   |
| 14. | Pilar Lim-Navarro, PhD            | - | United Laboratories, Inc.                                  |
| 15. | Gloria D. Manalo, PhD             | - | UP, Retired Professor                                      |
| 16. | Prof. Jocelyn Palacpac            | - | UP College of Pharmacy                                     |
| 17. | Prof. Marissa L. Panganiban       | - | UP, College of Pharmacy                                    |
| 18. | Prof. Ernesta G. Quintana         | - | UPLB, Dept. of Horticulture                                |
| 19. | Isidro Sia, PhD                   | - | UP College of Medicine                                     |
| 20. | Prof. Priscilla M. Torres         | - | UST, Faculty of Pharmacy                                   |
| 21. | Ms. Cherry V. Alim                | - | Bureau of Food and Drugs                                   |
| 22. | Ms. Helen Balde                   | - | Bureau of Food and Drugs                                   |
| 23. | Ms. Caroline Imelda B. Biares     | - | Bureau of Food and Drugs                                   |
| 24. | Ms. Haydee R. Boton               | - | Bureau of Food and Drugs                                   |
| 25. | Ms. Erwina Y.G. de Castro         | - | Bureau of Food and Drugs                                   |
| 26. | Ms. Guinevere S. Edralin          | - | Bureau of Food and Drugs                                   |
| 27. | Ms. Lucila R. Javier              | - | Bureau of Food and Drugs                                   |
| 28. | Ms. Rosario Martin                | - | Bureau of Food and Drugs                                   |
| 29. | Ms. Gloria Menano                 | - | Bureau of Food and Drugs                                   |
| 30. | Ms. Regina S. Obligacion          | - | Bureau of Food and Drugs                                   |
| 31. | Ms. Jennifer M. Oribello          | - | Bureau of Food and Drugs                                   |
| 32. | Ms. Lanette Lee A. Querubin       | - | Bureau of Food and Drugs                                   |
| 33. | Ms. Teresita D. Romero            | - | Bureau of Food and Drugs                                   |
| 34. | Ms. Ma. Theresa Pia Yap           | - | Bureau of Food and Drugs                                   |

### C. TWG on General Considerations

**Group Leader - Mr. Reynaldo Umali**

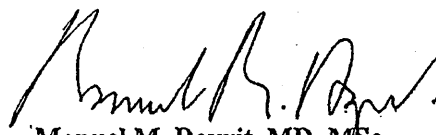
**Asst. Group Leader - Benigno Pecson, PhD**

- |    |                         |                        |
|----|-------------------------|------------------------|
| 1. | Atty. Froilan Bagabaldo | UP College of Pharmacy |
|----|-------------------------|------------------------|

- |     |                            |   |  |
|-----|----------------------------|---|--|
| 2.  | Magdalena C. Cantoria, PhD | - | UP College of Pharmacy / NAST          |
| 3.  | Prof. Ludivina de Padua    | - | UPLB, Institute of Biological Sciences |
| 4.  | Ms. Estelita N. Garcia     | - | Retired, Industrial Pharmacist         |
| 5.  | Ms. Rosalina Nolasco       | - | Swiss Pharma, Inc.                     |
| 6.  | Ms. Ofelia M. Alba         | - | Bureau of Food and Drugs               |
| 7.  | Ms. Zenaida Baumann        | - | Bureau of Food and Drugs               |
| 8.  | Ms. Florita Descallar      | - | Bureau of Food and Drugs               |
| 9.  | Ms. Grace Gianan           | - | Bureau of Food and Drugs               |
| 10. | Ms. Nazarita T Lanuza      | - | Bureau of Food and Drugs               |
| 11. | Ms. Rhoda Laine Manaloto   | - | Bureau of Food and Drugs               |
| 12. | Ms. Rosario Martin         | - | Bureau of Food and Drugs               |
| 13. | Ms. Araceli Torres         | - | Bureau of Food and Drugs               |

The members of the DOH Pharmacopeial Organization shall pursue the goals and the objectives of the Philippine Pharmacopeia Project towards the establishment of The Pharmacopeia of the Republic of the Philippines.

The maintenance and other operating expenses of the DOH Pharmacopeial Organization shall be charged against the BFAD funds and NDP funds sub-allotted to BFAD subject to the usual accounting and auditing rules and regulations.

  
**Manuel M. Dayrit, MD, MSc,**  
**Secretary of Health**





09 November 2004

**DEPARTMENT ORDER**

No. 2056, s. 2004

**Subject: Amending Department Order No. 352-F, s. 2001, The DOH Pharmacopeial Organization for the Preparation and the continuous Publication of the Philippine Pharmacopeia**

In order to fully accomplish the objectives of the Philippine Pharmacopeia Project of the Department of Health, Department Order No. 352, s. 2001 is hereby amended to include new members and provide for its reorganization.

The DOH Pharmacopeial Organization shall have the following members:

**A. Executive Board**

Leticia-Barbara B. Gutierrez, MS - Chair  
Conrado S. Dayrit, MD  
Natividad F. De Castro, PhD  
Quintin L. Kintanar, MD, PhD  
William D. Torres, PhD  
Pacita L. Zara, MD

**B. Project Manager** - Maria Lourdes C. Santiago  
**Assistant Project Manager** - Josephine K. Sarau, MSc  
**Technical Secretary** - Teresa A. Malabanan

**C. Steering Committee**

Froilan A. Bagabaldo, LLB  
Magdalena C. Cantoria, PhD  
Ludivina S. De Padua, MSc  
Estelita N. Garcia, BBM, MSc  
Cleotilde H. How, MD  
Alfonso T. Lagaya, MD  
Norma V. Lerma, Phar D, ScD  
Abraham F. Pascual, MD  
Benigno D. Peczon, PhD  
Reynaldo Maxlito H. Umali, MBA

***"Smoking is Dangerous to your Health"***

## **Technical Working Groups (TWG)**

### **A. Members of Technical Working Group on Monographs of Pharmaceutical Products, Part I**

**Estelita N. Garcia, BBM, MSc - Chair**

**Ofelia M. Alba, MM  
Alma A. Aguinaldo  
Marian M. Andaluz  
Jocelyn S. Babaan  
Jocelyn E. Balderrama  
Ma. Rosario B. Barangan  
Girle D. Bautista  
Pia Rose A. Belarmino  
Susana D. Calambro, MSc  
Modesto Chua, PhD  
Linda A. Cosico  
Belma A. Del Campo  
Rosario M. Dela Cruz  
Florlita Ma. H. Gabuna  
Therese Iryne R. Gonzales  
Cleotilde H. How, MD  
Cecilia A. Isaac, MD  
Sotera G. Jordan  
Virginia Francia C. Laboy  
Luzviminda O. Marquez  
Juvy Pilar M. Montillano, MPH  
Shemaine O. Ocheda  
Celia L. Ong  
Rizalina A. Opinion, MPA  
Marina O. Osi, PhD  
Liza S. Pajarillo  
Annie P. Rimando  
Frances Evelyn P. Robles  
Maria Lourdes C. Santiago  
Josephine K. Sarau, MSc  
Esther E. Velarde  
Jocelyn S. Vargas  
Estrella Paje-Villar, MD  
Yolanda O. Zurita**

**B. Members of Technical Working Group on Monographs of Crude Plant Drugs, Part II**

**Magdalena C. Cantoria PhD - Chair**

**Alicia M. Aguinaldo, PhD  
Cherry V. Alim  
Adoracion T. Arañez, PhD  
Lisa A. Asuncion, PhD  
Helen A. Balde, DipFDA  
Eliseo T. Banaynal, Jr., MD  
Caroline Imelda B. Fujishiro  
Haydee R. Boton  
Inocencio E. Buot, Jr., PhD  
Nelia P. Cortes-Maramba, MD  
Lourdes J. Cruz, PhD  
Fabian M. Dayrit, PhD  
Eduardo P. De Leon, DMD  
Ludivina S. De Padua, MSc  
Francis Wade Z. Gomez, MD, MPH  
Leticia-Barbara B. Gutierrez, MS  
Alfonso T. Lagaya, MD, MDM  
Norma V. Lerma, PhD, ScD  
Pilar Rizalina T. Lim-Navarro, PhD  
Maria Evelyn V. Mago  
Gloria D. Manalo, PhD  
Nida A. Mangmang, MBA  
Gloria L. Meñano  
Regina S. Obligacion  
Jocelyn S. Bautista-Palacpac, MSc  
Guinevere E. Pastrana  
Lanette Lee A. Querubin  
Ernesta G. Quintana, MSc  
Teresita D. Romero  
Isidro C. Sia, MD  
Priscilla M. Torres, MSc  
Ma. Theresa Pia C. Yap**

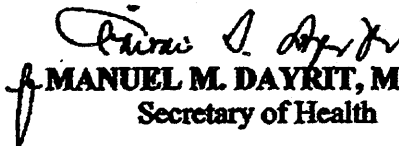
**C. Members of Technical Working Group on General Considerations, Part III**

**Reynaldo Maxlito H. Umali, MBA - Chair**

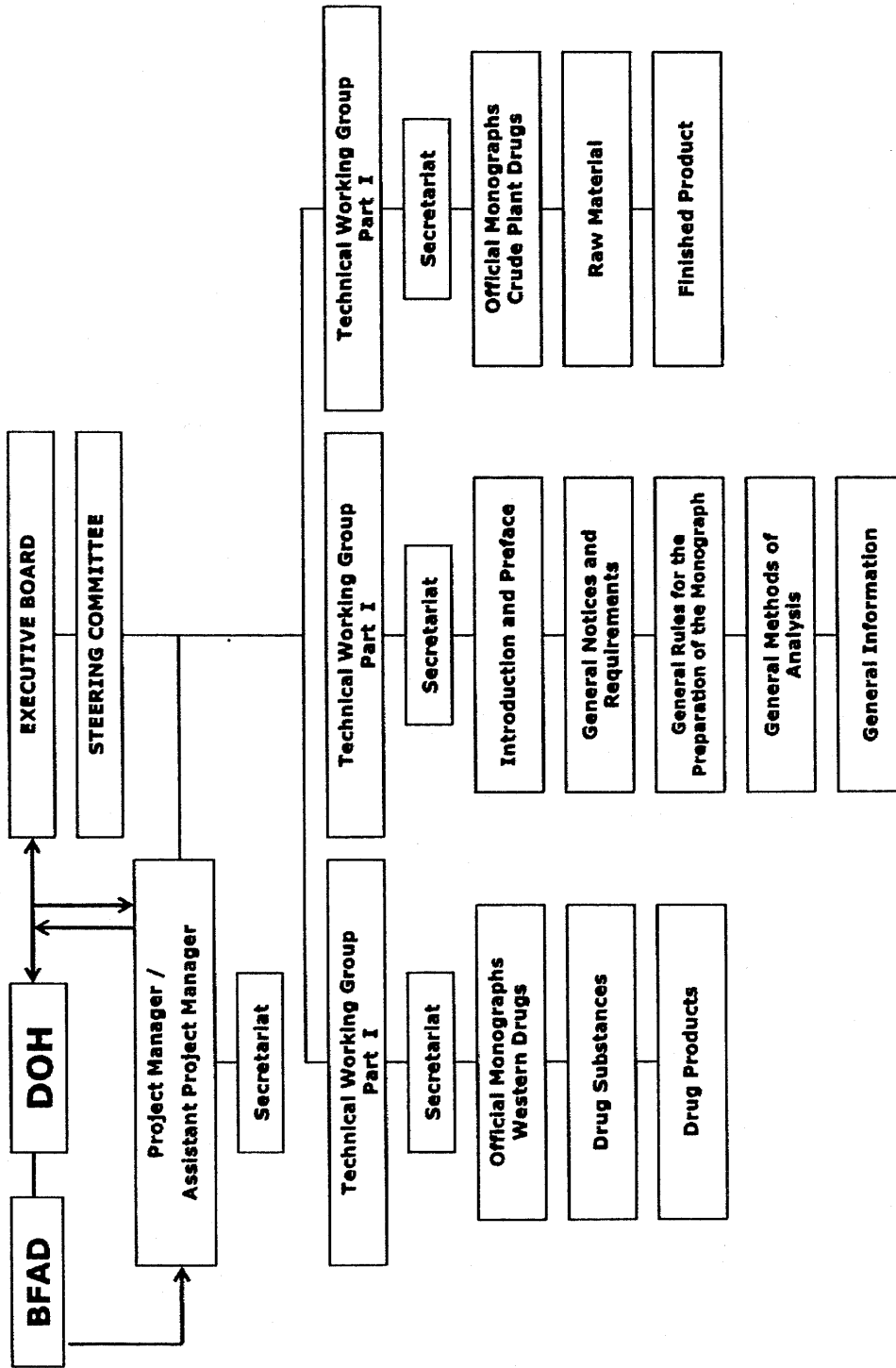
**Ofelia M. Alba, MM  
Froilan A. Bagabaldo, LLB  
Magdalena C. Cantoria, PhD  
Jesusa Joyce N. Cirunay, MSc  
Marita T. De Chavez  
Ludivina S. De Padua, MSc  
Ireneo M. Galicia, LLB  
Estelita N. Garcia, BBM, MSc  
Ma. Gracia A. Gianan-Recuenco  
Therese Irynne R. Gonzales  
Quintin L. Kintanar, MD, PhD  
Nazarita T. Lanuza, MPA  
Norma V. Lerma, Phar D, ScD  
Pilar Rizalina T. Lim-Navarro, PhD  
Marvin C. Malonzo  
Rhoda Laine D. Manaloto, MGM  
Rosario E. Martin  
Florita D. Moraleja  
Rosalina D. Nolasco  
Luz N. Pagaran  
Benigno D. Peczon, PhD  
Maria Lourdes C. Santiago  
Josephine K. Saran, MSc  
Araceli A. Torres**

**The members of the DOH Pharmacopeial Organization shall pursue the goals and the objectives of the Philippine Pharmacopeia Project towards the establishment of the Republic of the Philippines' Pharmacopeia, its supplements and succeeding editions.**

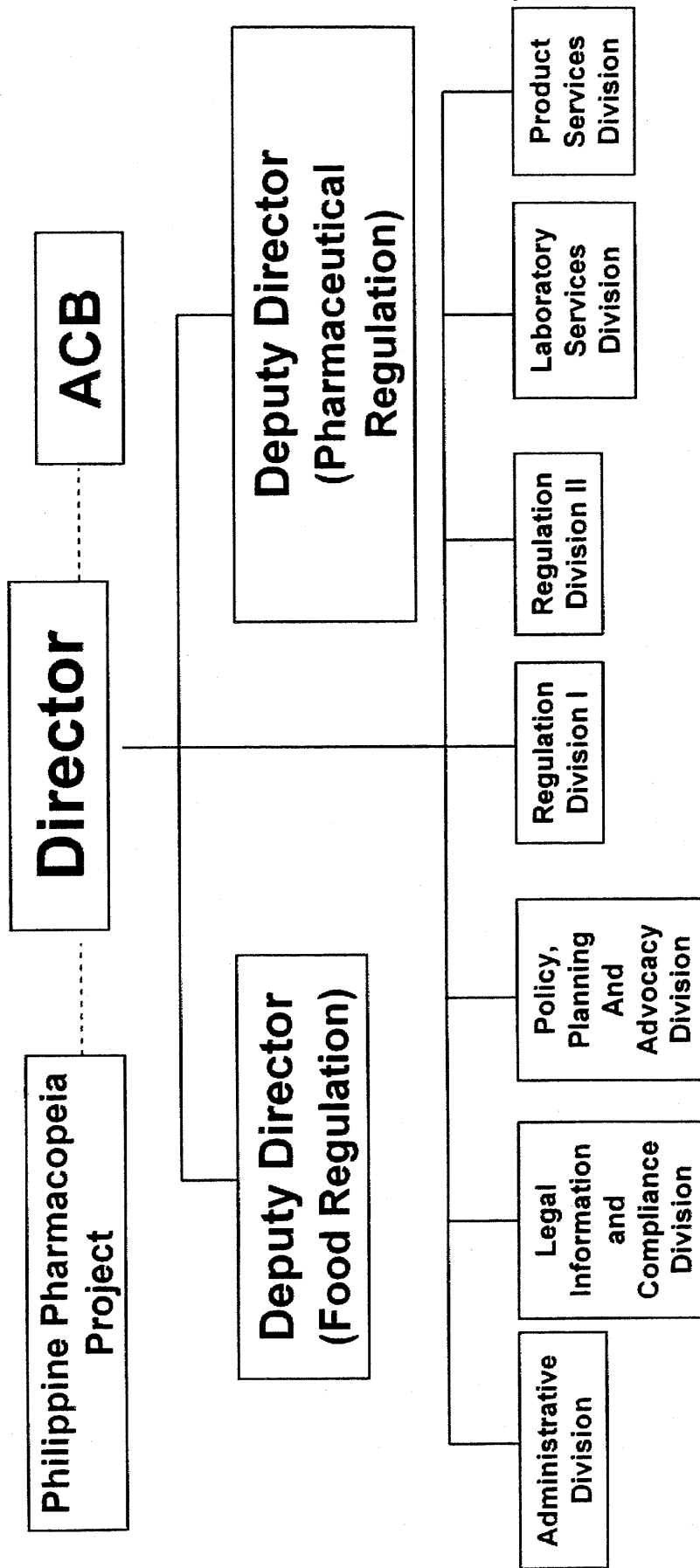
**The maintenance and other operating expenses of the DOH Pharmacopeial Organization shall be charged against BFAD funds subject to the usual accounting and auditing rules and regulations.**

  
**MANUEL M. DAYRIT, MD, MSc**  
**Secretary of Health**

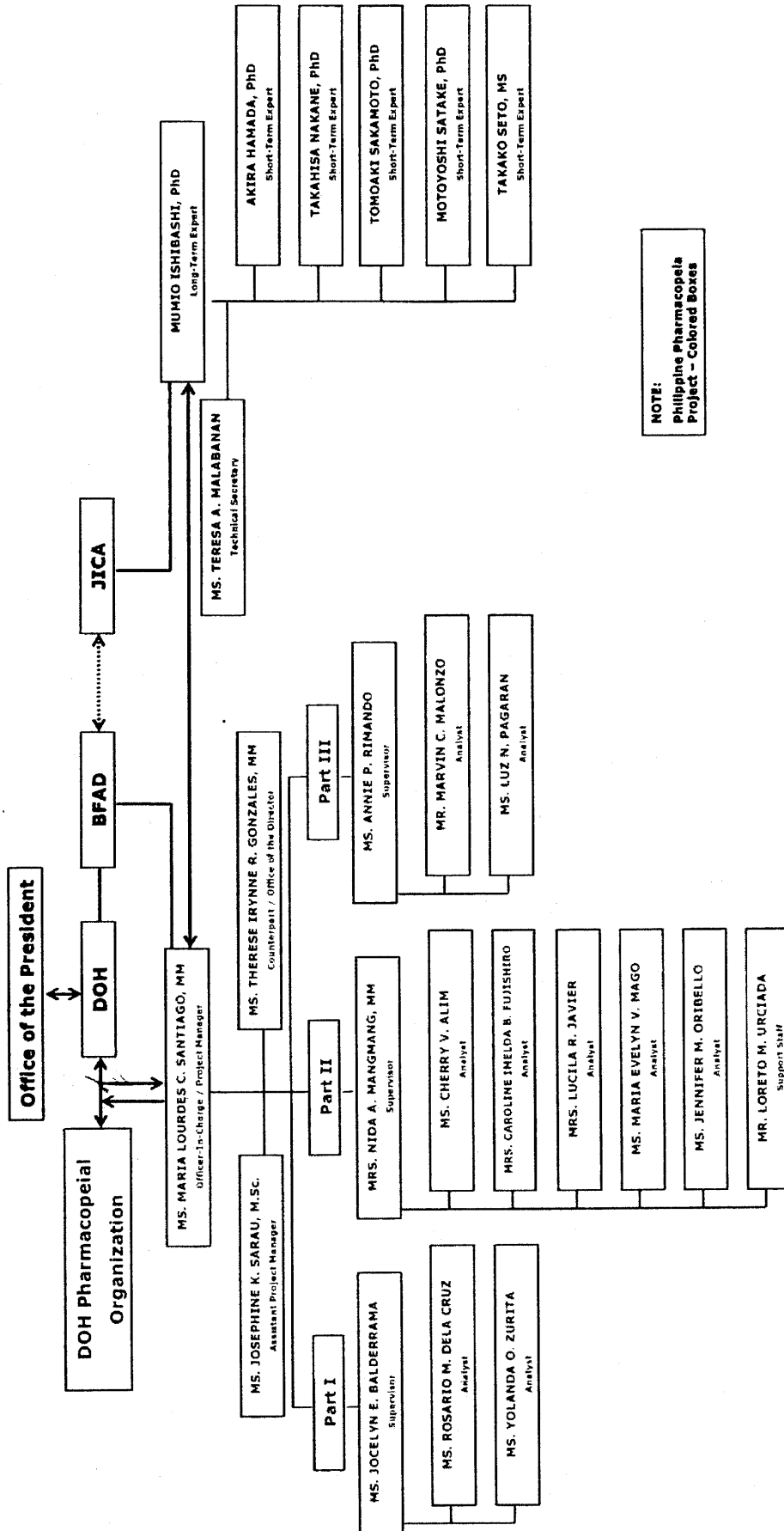
# The DOH Pharmacopeial Organization



# BFAD Organizational Structure



# PHILIPPINE PHARMACOPEIA PROJECT



NOTE:  
Philippine Pharmacopeia  
Project - Colored Boxes

11. フィリピン薬局方第1版制定の公式文書（政令第302号）

**Philippine Pharmacopeia 1**  
**Legal Mandate**



Office of the President  
of the Philippines  
Malacañang

Manila, March 31, 2004

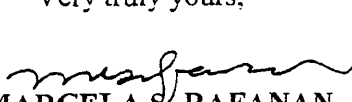
HON. MANUEL M. DAYRIT  
Secretary  
Department of Health  
Rizal Avenue, Sta. Cruz  
Manila

DEPARTMENT OF HEALTH	
Office of the Secretary	
Received by:	
Date	: APR 02 2004
E743-32-01 to 25 Loc. 1132 & 1134	
Code:	Z 224-2

Sir:

I have the honor to transmit for your information and guidance, a certified copy of Executive Order No. 302 dated March 29, 2004 entitled "**DECLARING AND ADOPTING THE PHILIPPINE PHARMACOPEIA AS THE OFFICIAL BOOK OF STANDARDS AND REFERENCE FOR PHARMACEUTICAL PRODUCTS AND CRUDE PLANT DRUGS IN THE PHILIPPINES.**"

Very truly yours,

  
MARCELA S. RAFANAN

Director IV  
Malacañang Records Office

gld.

**MALACAÑANG**  
Manila

**EXECUTIVE ORDER NO. 302**

**DECLARING AND ADOPTING THE PHILIPPINE PHARMACOPEIA AS THE  
OFFICIAL BOOK OF STANDARDS AND REFERENCE FOR  
PHARMACEUTICAL PRODUCTS AND CRUDE PLANT DRUGS IN THE  
PHILIPPINES**

**WHEREAS**, it is State Policy under Article II, Section 15 of the 1987 Constitution to "protect and promote the right to health of the people and instill health consciousness among them";

**WHEREAS**, the 1987 Constitution also provides in Article XIII, Section 12, that: "The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems";

**WHEREAS**, a national pharmacopeia that adequately establishes standards for drug/drug products and crude drugs available in commerce in the Philippines is essential to the attainment of an effective regulatory and health care delivery systems and addresses the foregoing constitutional mandates;

**NOW, THEREFORE, I, GLORIA MACAPAGAL-ARROYO**, President of the Philippines, do hereby order:

SECTION I. The Philippine Pharmacopeia (PP) 1st edition April 2004 and any supplement thereto, is hereby declared and adopted as the official book of standards and references for the determination of the identity, purity, and quality of pharmaceutical products and crude plant drugs in the Philippines.

SECTION 2. For pharmaceutical products and crude plant drugs that are not listed in the PP, reference maybe made to the latest editions of United States Pharmacopeia/National Formulary (USP/NF), Japanese Pharmacopeia (JP), British Pharmacopeia (BP) European Pharmacopeia (EP), and International Pharmacopeia (IP) and other books of standards and references as maybe recognized and adopted by the Bureau of Food and Drugs from time to time.

SECTION 3. All orders, issuances, rules and regulations, or parts thereof inconsistent with this Executive Order are hereby repealed or modified accordingly.



SECTION 4. This Executive Order shall take effect fifteen (15) days after publication in the Official Gazette.

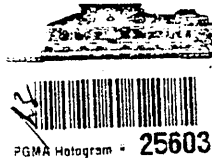
Done in the City Manila this 29<sup>th</sup> day of March, in the year of Our Lord, two thousand and four.

*Glenn Arango*



By the President:

*Alberto G. Romulo*  
**ALBERTO G. ROMULO**  
Executive Secretary



CERTIFIED COPY:  
*Marcela S. Rafanan*  
MARCELA S. RAFANAN  
DIRECTOR IV  
Malacañang Records Office  
843-31-04  
4.1.11



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**  
San Lazaro Cmpd., Rizal Ave.  
Sta. Cruz, Manila, Philippines 1103  
Tel. = (632) 743-8301



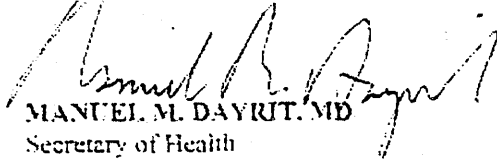
15 April 2004

DEPARTMENT CIRCULAR NO. 133 s. 2004

TO

UNDERSECRETARIES OF HEALTH, PRESIDENT OF PHIC,  
CHAIRMAN OF THE DDB, CHAIRMAN OF PITAHC, ALL  
BUREAU/SERVICE DIRECTORS, HEADS OF UNIT, AND  
CHIEFS OF HOSPITALS AND OTHER CONCERNED

FROM

  
MANUEL M. DAYRIT, MD  
Secretary of Health

SUBJECT

*Declaring and Adopting the Philippine Pharmacopeia as the Official  
Book of Standards and References for Pharmaceutical Products and  
Crude Plant Drugs in the Philippines*

This refers to Executive Order No. 302 dated March 29, 2004, Declaring and Adopting the Philippine Pharmacopeia as the Official Book of Standards and Reference for Pharmaceutical Products and Crude Plant Drugs in the Philippines by Her Excellency Gloria Macapagal-Arroyo.

For your information and strict compliance

12. BFAD から JICA への要請文書（薬局方改訂のための継続的協力）



REPUBLIC OF THE PHILIPPINES  
**DEPARTMENT OF HEALTH**  
**BUREAU OF FOOD AND DRUGS**  
Civic Drive, Filinvest Corporate City  
Alabang, Muntinlupa City



MALAYA AT MALUSOG  
NA PAMAYANAN

25 November 2004

**SHOZO MATSUURA**

Resident Representative  
Japan International Cooperation Agency  
Makati City

Dear **Mr. Matsuura**:

This refers to the Philippine Pharmacopeia Project which is scheduled to end in April 2005.

We would like to extend our sincere appreciation for all the support that you have provided to make this Project successful. The Philippine Pharmacopeia 1 (PP1) has been launched and Executive Order No. 302 was issued by Her Excellency, President Gloria Macapagal-Arroyo adopting the said book as the official reference book of standards for the determination of the identity, purity and quality of pharmaceutical products and crude plant drugs. However, continues research work is still being done for the supplement of PP1 and the succeeding editions which we have decided to publish every five years.

In view of the termination of the Project in April 2005, we would like to take this opportunity to request the following:

1. provision of a short-term expert to BFAD, once a year for a 5-year duration
2. assistance for the maintenance of all the equipment being used in the Project

Your approval of the above requests will surely help us in the preparation and publication of the succeeding editions of the Philippine Pharmacopeia.

We look forward to your positive response and thank you very much for your kind attention.

Very truly yours,

  
**PROF. LETICIA-BARBARA B. GUTIERREZ, MS**  
Director