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E.O. 12356: N/A  
TAGS: EIND, ETRD, EINV, BR  
SUBJECT: TRANSLATION OF DRAFT DECREE REGULATING  
- PHARMACEUTICALS/FINE CHEMICALS

REF: BRASILIA 8172

1. FOLLOWING IS CONSULATE'S INFORMAL TRANSLATION OF DRAFT DECREE AS REPORTED IN "FOLHA DE SAO PAULO" ON JULY 9. TRANSLATION WAS SENT VIA POUCH TO BRASILIA, RIO, ARA/BR, USDOC, AND USTR ON JULY 22.

2. BEGIN TRANSLATION: THE PRESIDENT OF THE REPUBLIC, USING THE POWERS CONFERRED ON HIM BY ARTICLE 81, ITEM III OF THE FEDERAL CONSTITUTION, AND IN ACCORDANCE WITH THE GUIDELINES SET FORTH IN THE FIRST NATIONAL DEVELOPMENT PLAN OF THE NEW REPUBLIC, DECREES:

ART. 1 - AMONG THE OBJECTIVES OF THE GOVERNMENT'S INDUSTRIAL POLICY ARE THE DEVELOPMENT OF THE NATIONAL PHARMACEUTICAL CHEMICAL INDUSTRY, AND ITS CONSOLIDATION,

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THROUGH MEASURES DESIGNED TO:

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UNITED STATES DEPARTMENT OF STATE  
REVIEW AUTHORITY: NORMAN M. BOUTON  
DATE/CASE ID: 19 DEC 2001 200000143

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- A) INCREASE THE INTERNAL PRODUCTION OF ESSENTIAL SPECIALTY CHEMICALS, GIVING PRIORITY TO COMPANIES UNDER EFFECTIVE NATIONAL CONTROL;
  - B) REDUCE THE HIGH DEGREE OF DEPENDENCE ON FOREIGN SOURCES OF SUPPLY OF PRODUCTS AND TECHNOLOGIES;
  - C) ADAPT THE INTERNAL SUPPLY OF MEDICINES, SPECIALTY CHEMICALS, AND PHARMACEUTICAL RAW MATERIALS TO BRAZILIAN HEALTH AND INDUSTRIAL POLICIES;
  - D) PERFECT THE SYSTEM OF QUALITY CONTROL FOR AND INSPECTION OF THE PRODUCTION, DISTRIBUTION, AND ADVERTISING OF MEDICINES, SPECIALTY CHEMICALS, AND PHARMACEUTICAL RAW MATERIALS, IN ORDER TO MINIMIZE THE RISKS TO CONSUMERS' HEALTH AND TO PROTECT NATIONAL INDUSTRY;
  - E) EXTEND THE GOVERNMENT'S PHARMACEUTICAL ASSISTANCE TO ALL THE NEEDY POPULATION.
- (1) - ALSO AMONG THE GOALS SET FORTH IN THIS ARTICLE IS THE INTEGRATION OF INTERNAL PRODUCTION, BY INCREASING THE PRODUCTION OF INTERMEDIATE PRODUCTS IN ORDER TO GUARANTEE ECONOMIES OF SCALE AND TECHNICAL EFFICIENCY.
  - (2) - THE PHARMACEUTICAL CHEMICAL INDUSTRY CONCEPT INCLUDES PRODUCTS BOTH FOR HUMAN AND VETERINARY USE.

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- ART. 2 - IMPLEMENTATION OF THE INDUSTRIAL POLICY FOR THE PHARMACEUTICAL CHEMICAL SECTOR WILL BE CARRIED OUT THROUGH THE COMBINED EFFORTS OF THE VARIOUS ORGANS OF GOVERNMENT DIRECTLY OR INDIRECTLY LINKED TO THE SECTOR, BE COORDINATED BY THE INDUSTRIAL DEVELOPMENT COUNCIL (CDI), AND WILL TAKE INTO ACCOUNT THE GUIDE-LINES AND SPECIFIC POLICIES INDICATED IN THE FOLLOWING ARTICLES

- ART. 3 - IN CONFORMANCE WITH THE GOALS SET FORTH IN ARTICLE 1, IN ANALYZING AND SELECTING PROJECTS IN THE SECTOR THE INDUSTRIAL DEVELOPMENT COUNCIL (CDI) WILL GIVE

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PREFERENCE TO THOSE COMPANIES WHICH, TAKING INTO ACCOUNT THE CRITERIA OF TECHNICAL, ECONOMIC, AND ADMINISTRATIVE EFFICIENCY, IN ACCORDANCE WITH THEIR SIZE:

- A) POSSESS CONTROL OVER THE PROCESS OF TECHNICAL DECISION-MAKING;
- B) PRODUCE THE GREATEST NATIONAL ADDED VALUE, PRESERVING EFFICIENCY LEVELS COMPATIBLE WITH THE BRAZILIAN MARKET;
- C) CONTRIBUTE TO THE INTEGRATION OF THE CHEMICAL INDUSTRY'S PRODUCTIVE PARK, IN TECHNOLOGICAL, ECONOMIC, AND ENTREPRENEURIAL TERMS;
- D) COMMIT THEMSELVES TO CARRY OUT DEFINED PROGRAMS, WHICH INCORPORATE, IN THE FOLLOWING ORDER, DEVELOPMENT AND ABSORPTION OF TECHNOLOGY;
- E) PROMOTE, WHEN VIABLE, THE POLICY OF OFFERING THEIR STOCK TO THE PUBLIC;
- F) MAXIMIZE THE UTILIZATION OF NATIONAL TECHNOLOGY, GOODS, AND SERVICES;

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TAGS: EIND, ETRD, EINV, BR  
SUBJECT: TRANSLATION OF DRAFT DECREE REGULATING

- G) IN PHARMACEUTICAL CHEMICAL SECTOR PROJECTS FOR HUMAN USE, GIVE PRIORITY TO THE PRODUCTION OF:

- 1 - SPECIALTY CHEMICALS AND PHARMACEUTICAL RAW MATERIALS USED IN THE MEDICINES CONTAINED IN THE NATIONAL REGISTER OF ESSENTIAL MEDICINES (RENAME);

- 2 - SPECIALTY CHEMICALS DERIVED FROM NATURAL PRODUCTS AVAILABLE WITHIN THE COUNTRY.

- UNIQUE PARAGRAPH - INVESTMENTS IN THIS SECTOR WILL BE CARRIED OUT IN ACCORDANCE WITH THE ADEQUATE IMPLEMENTATION OF PROJECTS WHICH ASSURE EFFICIENT UTILIZATION OF NATIONAL SAVINGS.

- ART. 4 - IN CONFORMANCE WITH SPECIFIC LEGAL  
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DISPOSITIONS IN EFFECT, AND AFTER CONSULTING THE EXECUTIVE SECRETARIAT OF THE INDUSTRIAL DEVELOPMENT COUNCIL, THE CUSTOMS POLICY COMMISSION (CPA) WILL ESTABLISH THE TARIFF POLICY FOR THE SECTOR ALONG THE FOLLOWING BASIC PARAMETERS:

- A) TARIFF GRADUATION WHICH ENCOURAGES VERTILIZATION OF THE PRODUCTION OF SPECIALTY CHEMICALS AND PHARMACEUTICAL RAW MATERIALS;

- B) OBSERVANCE OF THE INDICES OF NATIONALIZATION PRE-ESTABLISHED BY THE CDI FOR GRANTING REDUCTIONS IN THE DUTIES ON IMPORTED INTERMEDIATE PRODUCTS;

- C) ADEQUATE PROTECTION FOR NATIONAL PRODUCTION.

- ART. 5 - THE NATIONAL HEALTH SURVEILLANCE SECRETARIAT WILL AUTHORIZE THE IMPORTATION OF MEDICINES, SPECIALTY CHEMICALS, AND PHARMACEUTICAL RAW MATERIALS ONLY WHEN THE FOLLOWING REQUIREMENTS ARE OBSERVED:

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- A) THEY CONFORM WITH THE BRAZILIAN PHARMACOLOGICAL STANDARDS, THE NATIONAL FORMULARY, AND OTHER APPLICABLE NORMS;
- B) IT CONFIRMS THAT SIMILAR INTERNAL PRODUCTION DOES NOT EXIST, IS INSUFFICIENT, OR IS DESTINED FOR CAPITVE CONSUMPTION OR AN EXCLUSIVE CLIENTELE;
- C) AN INCREASE IN COMPETITION IN THE INTERNAL MARKET IS CONVENIENT.

- UNIQUE PARAGRAPH - THE NATIONAL HEALTH SURVEILLANCE  
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SECRETARIAT, IN CONJUNCTION WITH THE CDI, PERIODICALLY WILL PUBLISH THE REGISTER OF THOSE SPECIALTY CHEMICALS AND PHARMACEUTICAL RAW MATERIALS WHICH CAN BE IMPORTED ONLY WITH THE PRIOR AUTHORIZATION REFERRED TO IN THIS ARTICLE.

- ART. 6 - WHEN ISSUING IMPORT LICENSES, THE FOREIGN TRADE DEPARTMENT OF THE BANK OF BRAZIL (CACEX) WILL VERIFY WHETHER THE PHARMACEUTICAL RAW MATERIALS CAN BE FOUND ON THE CERTIFICATES AUTHORIZING PRODUCTION GRANTED BY THE NATIONAL HEALTH SURVEILLANCE SECRETARIAT.

- UNIQUE PARAGRAPH - CACEX, IN CONJUNCTION WITH THE CDI, ANNUALLY WILL COMPILE STATISTICS ON THE IMPORTATION AND EXPORTATION OF SPECIALTY CHEMICALS AND PHARMACEUTICAL RAW MATERIALS ON A DISAGGREGATED BASIS, BY WEIGHT, VALUE, ORIGIN, AND DESTINATION, SO THAT THE INFORMATION CAN BE UTILIZED TO EXECUTE THE POLICY ESTABLISHED BY THIS DECREE.

- ART. 7 - THE FEDERAL REVENUE SECRETARIAT, IN CONJUNCTION WITH THE MINISTRY OF HEALTH, WILL CARRY OUT THE SYSTEMATIC VERIFICATION OF THE DECLARED IDENTITY AND QUALITY OF IMPORTED SPECIALTY CHEMICALS AND PHARMACEUTICAL RAW MATERIALS AT THE TIME THEY ARE UNLOADED IN THE COUNTRY.

- ART. 8 - IN CONFORMANCE WITH THE SPECIFIC LEGAL DISPOSITIONS IN EFFECT, THE INTERMINISTERIAL PRICE COUNCIL WILL ADJUST ITS PRICE CONTROL POLICY FOR THE

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SECTOR TO CONFORM TO THE GOALS EXPOUNDED IN ART. 1, BOTH AT THE LEVELS OF SPECIALTY CHEMICALS AND PHARMACEUTICAL RAW MATERIALS AND OF MEDICINES, BASED ON A PROPOSAL TO BE PREPARED BY THE MINISTRIES OF FINANCE AND OF INDUSTRY AND COMMERCE.

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E.O. 12356: N/A  
TAGS: EIND, ETRD, EINV, BR  
SUBJECT: TRANSLATION OF DRAFT DECREE REGULATING

- ART. 9 - IN ORDER TO RATIONALIZE THE DISTRIBUTION OF SPECIALTY CHEMICALS, THE ORGANS AND ENTITIES OF DIRECT AND INDIRECT FEDERAL ADMINISTRATION, AND FOUNDATIONS UNDER ITS SUPERVISION, WILL ENFORCE FULL ADOPTION OF THE BRAZILIAN COMMON DESTINATION (DCB), BOTH IN INTERNAL AND FOREIGN TRADE, FACILITATING THE SIMULTANEOUS USE OF COMMERCIAL TRADEMARKS FOR MEDICINES.

- ART. 10 - HENCEFORTH FOR ITS PURCHASE POLICY THE MEDICINES CENTRAL (CEME) WILL ADOPT THE FOLLOWING CRITERIA:

- A) IN ACQUIRING MEDICINES, AS A CRITERIA FOR JUDGING

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SUPPLIERS' BIDS THE CEME WILL CONSIDER THE UTILIZATION OF SPECIALTY CHEMICALS AND PHARMACEUTICAL RAW MATERIALS WHICH COMPLY WITH THE NATIONALIZATION INDICES SET BY THE CDI FOR THE FORMULATION OF CEME SPECIALTY DRUGS;

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- B) IN PURCHASING SPECIALTY CHEMICALS AND PHARMACEUTICAL RAW MATERIALS, THE CEME WILL ACQUIRE THOSE WHICH MEET THE NATIONALIZATION INDICES SET BY THE CDI;

- C) IN THE CASE OF THOSE SPECIALTY CHEMICALS AND PHARMACEUTICAL RAW MATERIALS FOR WHICH NO FIXED INDICES OF NATIONALIZATION EXIST, THAT POLICY WILL BE ADOPTED WHICH MOST CLOSELY CONFORMS TO THE GOALS SET FORTH IN ART. 1 OF THIS DECREE.

- UNIQUE PARAGRAPH - THE EXECUTIVE SECRETARIAT OF THE INDUSTRIAL DEVELOPMENT COUNCIL AND THE MEDICINES CENTRAL, IN CONJUNCTION, WILL SET THE CRITERIA AND CONDITIONS TO BE OBSERVED IN DRAWING UP THE NATIONALIZATION PLANS TO WHICH THIS ARTICLE REFERS.

- ART. 11 - IN THE AREA OF DISTRIBUTION, THOSE PUBLIC AND PRIVATE ENTITIES WHICH MAINTAIN AGREEMENTS FOR THE PROVISION OF HEALTH SERVICES ALSO WILL BE ENCOURAGED TO INCREASINGLY USE THOSE MEDICINES CONTAINED IN THE NATIONAL REGISTER OF ESSENTIAL MEDICINES (RENAME).

- ART. 12 - THE NATIONAL HEALTH SURVEILLANCE SECRETARIAT WILL BE GIVEN THE MEANS NECESSARY TO PERFECT THE SYSTEM FOR THE REGISTRATION AND CONTROL OF MEDICINES, BASED ON THE FOLLOWING CRITERIA:

- A) RIGID CONTROL OF THE REGISTRATION, OR THE RENEWAL OF REGISTRATION, OF MEDICINES WITH A HIGH RISK/BENEFIT RATIO, OF NO DEFINITELY PROVEN THERAPEUTIC VALUE, OR WHICH DO NOT REPRESENT A RELEVANT THERAPEUTIC ADVANTAGE OVER THOSE MEDICINES WHICH UTILIZE SPECIALTY CHEMICALS

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PRODUCED IN THE COUNTRY;

- B) SYSTEMATIC CONTROL OF THE QUALITY OF SPECIALTY CHEMICALS, PHARMACEUTICAL RAW MATERIALS, AND MEDICINES IN THE MARKET, OBSERVING BRAZILIAN NORMS;

- C) IN CONFORMANCE WITH SANITARY SURVEILLANCE LAWS AND THE INTERESTS OF HEALTH POLICY, AUTHORIZATION TO PRODUCE SPECIALTY CHEMICALS AND PHARMACEUTICAL RAW MATERIALS WILL BE GRANTED ONLY AFTER THE RESPECTIVE PROJECT HAS BEEN APPROVED BY THE INDUSTRIAL DEVELOPMENT COUNCIL.

- UNIQUE PARAGRAPH - RECEIVING AUTHORIZATION TO OPERATE DOES NOT EXEMPT A COMPANY FROM THE REQUIREMENT THAT IT OBTAIN THE CERTIFICATE OF AUTHORIZATION FOR THE PRODUCTION OF RAW MATERIALS, PHARMACEUTICAL RAW MATERIALS, AND ADDITIVES REFERRED TO IN LAW NO. 6,360 OF SEPTEMBER 23, 1976.

- ART. 13 - AFTER THE DATE THIS DECREE IS PUBLISHED, LICENSES OR REGISTRATION FOR SPECIALTY CHEMICALS AND PHARMACEUTICAL RAW MATERIALS USED TO MAKE PRODUCTS FOR VETERINARY USE, INCLUDING THOSE FOR THE INGREDIENTS OF ANIMAL FEED SUPPLEMENTS, REFERRED TO IN DECREE NO. 64,499 OF MAY 14, 1959, WILL BE GRANTED BY THE COMPETENT ORGAN OF THE MINISTRY OF AGRICULTURE ONLY IF THE RESPECTIVE INDUSTRIAL PROJECT HAS BEEN PREVIOUSLY APPROVED BY THE INDUSTRIAL DEVELOPMENT COUNCIL.

- UNIQUE PARAGRAPH - WITHIN SIXTY DAYS THE MINISTRY OF AGRICULTURE, IN CONJUNCTION WITH THE MINISTRY OF INDUSTRY AND COMMERCE, WILL PUBLISH A REGISTER OF THOSE MANUFACTURERS OF THE PRODUCTS COVERED BY THIS ARTICLE WHICH EXIST AS OF THIS DATE.

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- ART. 14 - BASED ON UNIFIED PROGRAMMING, THE VARIOUS AGENCIES PROMOTING TECHNOLOGY WILL ACT IN SUCH A MANNER AS TO CREATE A BASIC TECHNOLOGICAL INFRASTRUCTURE FOR THE SECTOR, WHICH WILL ASSURE ITS SELF-SUSTAINING DEVELOPMENT.

- ART. 15 - WITHIN LEGAL LIMITATIONS, GOVERNMENT LENDING AGENCIES MAY GRANT TO APPROVED INDUSTRIAL PROJECTS, AND THOSE FOR THE DEVELOPMENT OR ABSORPTION OF TECHNOLOGY, THE FOLLOWING TYPES OF RESOURCES:

- A) FINANCING TO THE COMPANY AND/OR SHAREHOLDERS UNDER THE MOST FAVORABLE CONDITIONS OF INTEREST RATES AND TERMS IN EFFECT AT THE TIME OF THE CONTRACT;

- B) PARTICIPATION IN RISK CAPITAL;

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- C) PROVISION OF A GUARANTEE (SECURITY DEPOSIT OR BOND) FOR CONTRACTS INVOLVING FOREIGN OR INTERNAL FINANCING;

- D) SUPPORT FOR STOCK OR BOND OFFERINGS IN CAPITAL MARKETS.

- ART. 16 - SECTORAL GROUP 3 - CHEMICAL, PETROCHEMICAL

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AND PHARMACEUTICAL INDUSTRIES, OF THE EXECUTIVE SECRETARIAT OF THE CDI, REFERRED TO IN ART. 5 OF DECREE NO. 81,651 OF MAY 11, 1978, FROM NOW ON WILL INCLUDE REPRESENTATIVES OF THE MINISTRY OF SCIENCE AND TECHNOLOGY (MCT), THE UNDERWRITER OF STUDIES AND PROJECTS S.A. (FINEP), AND THE MEDICINES CENTRAL (CEME).

- ART. 17 - IN HIS ROLE AS PRESIDENT OF THE INDUSTRIAL DEVELOPMENT COUNCIL THE MINISTER OF INDUSTRY AND COMMERCE CAN ENACT THOSE MEASURES NECESSARY TO REGULATE THIS DECREE.

SAO PAULO, JULY 18, 1986. END TRANSLATION. DACHI

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