

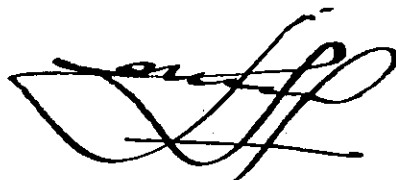
FOREWORD

In order to ensure the quality of veterinary drugs distributed in Indonesia, the Government of the Republic of Indonesia established the Veterinary Drug Assay Laboratory (VDAL) in Bogor, West Java with financial aid from the Government of Japan. This project is being implemented under a technical cooperation programme between the Government of the Republic of Indonesia and the Government of Japan. The executing agencies of both Governments are Directorate General of Livestock Services, Department of Agriculture and the Japan International Cooperation Agency (JICA), respectively. This project was started in April 1984 for 5 years and extended until 1991. Recently, the Technical cooperation as Aftercare Programme has been started since July, 1994 until June 1996.

The main functions of the laboratory are to examine the quality of veterinary drugs produced and imported as well as to monitor the quality of veterinary drugs on the market.

This booklet contains some information about the Veterinary Drug Assay Laboratory. It is hoped that the booklet will be useful for your information.

Bogor, March 13, 1995

A stylized, handwritten signature in black ink, likely belonging to Dr. Syamsul Bahri Siregar. The signature is fluid and cursive, with a prominent loop at the end.

Dr. Syamsul Bahri Siregar, M.Sc.
Director
Veterinary Drug Assay Laboratory

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HISTORICAL BACKGROUND

Veterinary drugs are one of effective tools for the control and prevention of animal diseases and the stable supply of good quality veterinary drugs is of great importance to livestock industry in order to ensure high productivity. There has been a growing demand among people involved in livestock industry for the institutional quality control of veterinary drugs to promote further development of the industry in this country. The Government of Indonesia realized the importance of veterinary drug control and planned to established the Veterinary Drug Assay Laboratory (VDAL) under the code number ATA-297. Then the Government requested grant capital aid of the Government of Japan to assist set up VDAL.

The Government of Japan positively responded to the request and dispatched a contact mission to look into problems concerned with veterinary drugs and investigate the necessity of a comprehensive assay system of veterinary drugs in November 1982. In March 1983, the Government of Japan dispatched a couple of survey teams together namely a preliminary survey team on technical cooperation and a basic design survey team for the construction of VDAL, to discuss technical and financial cooperation for VDAL. The teams concluded that VDAL would play a great role to ensure the quality of veterinary drugs distributed in Indonesia and contribute much to livestock development if it was established and technical cooperation extended. As a result, Diplomatic Notes were exchanged in September 1983 between the Government of Indonesia and the Government of Japan to construct VDAL with grant capital aid of the Government of Japan. In February 1984, the Record of Discussion on technical cooperation for VDAL was signed for the Japan International Cooperation Agency (JICA) to extend technical assistance for five years starting on 1st April 1984.

A site of 5,5 hectares was prepared for the construction of VDAL by the Government of Indonesia, which allocated counterbudget to construct ancillary facilities such as staff houses, a dormitory, fences around the premise, etc. The construction of the laboratory buildings started in March 1984 and completed in early January 1985, then turned over to the Government of Indonesia on 26th January 1985. On 30th April 1985, the Minister of Agriculture issued a decree concerning the fuctions and authority of VDAL and authorized VDAL to conduct the national assay and quality certification of veterinary drugs. The opening ceremony of VDAL was held on 2nd August and officially inaugurated by Ir. Achmad Affandi, Minister of Agriculture. On 4th February 1985 Yuntiwa Ramdan, D.V.M. was assigned to the Director of VDAL and succeeded by Syamsul Bahri Siregar, D.V.M. M.Sc. on 29th February 1988.

The technical cooperation has been progressing since April 1985. A number of Japanese experts have ben assigned for VDAL and Indonesian staff have been sent to Japan to study assay techniques and related subjects since the commencement of the cooperation. Equipment and other materials necessary for the VDAL activities have also been provided by the Government of Japan pursuant to the Record of Discussion. Once the technical cooperation has been closed on March 1989 and extended another 2 years until 1991. Recently, the technical cooperation as after care program has been started since July, 1994 until June 1996.

OBJECTIVES

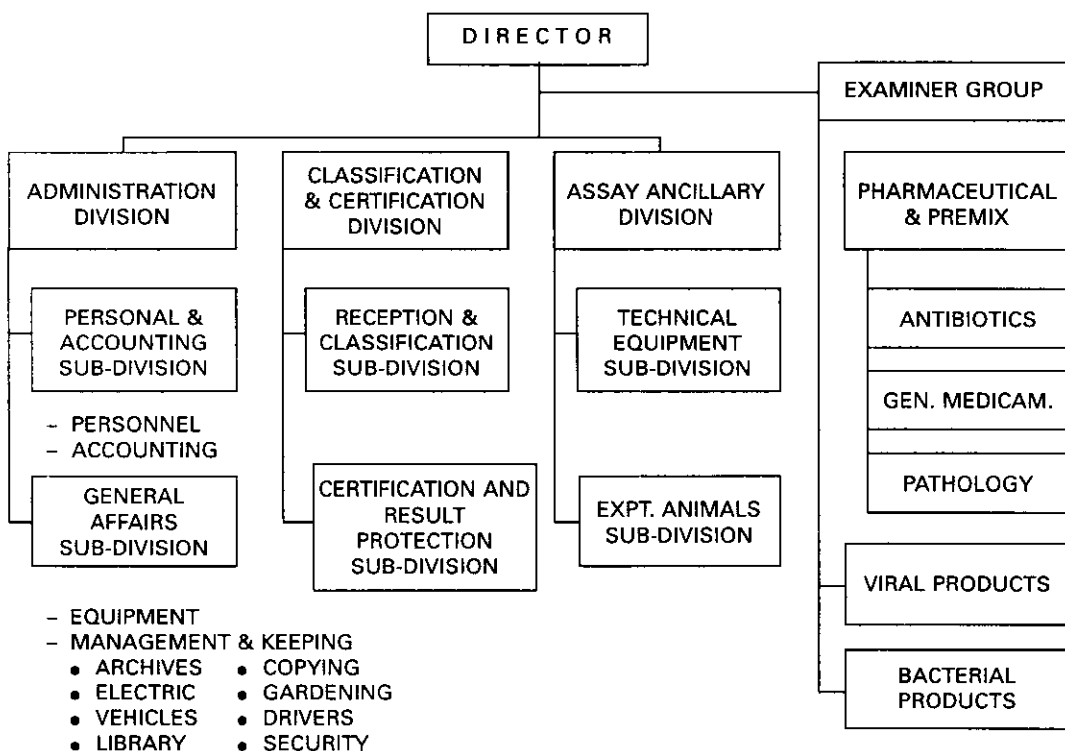
VDAL is charged with the task of a national scope to ensure the quality of veterinary drugs available in Indonesia and thus aims at contributing to the sound development of livestock industry.

The following are the main objectives of VDAL.

1. To ensure the quality of veterinary drugs distributed in Indonesia so that good quality veterinary drugs can be available to the user.
2. To set up quality certification system of veterinary drugs to guarantee their quality.
3. To develop better assay methods of veterinary drugs.

ORGANIZATION

VDAL is one of technical institutions concerned with animal health of the Directorate General of Livestock Services, Department of Agriculture, being charged with the quality control of veterinary drugs and directly responsible to Director General of Livestock Services.



STAFFING

1. The total number of staff is 96 as of March 1995, consisting of :

Veterinarian (including Director)	27
Technical asistants	34
Administrative staff	22
Labourers and drivers	13

2. Main staff

Director	: Syamsul Bahri Siregar, D.V.M., M.Sc.
Head of Assay Ancillary Division	: I Gusti Agung Gde Anom, D.V.M. (Acting)
– Chief of Technical Equipment Sub-Division	: Gatot Mudiarto, D.V.M. (Acting)
– Chief of Exp. Animal Sub-Division	: Liliek Indrayani, D.V.M. (Acting)
Head on Classification and Certification Division	: Endang Susanto, D.V.M. (Acting)
– Chief of Reception and Classification Sub-Division	: Sumadi, D.V.M.
– Chief of Certification and Result Protection Sub-Division	: Hasbullah, D.V.M., M.Sc., Ph.D. (Acting)
Head of Administration Division	: Rachmat Hasan Madsahal, B.Sc.
– Chief of Personal and Accounting Sub-Division	: M. Yusuf
– Chief of General Affair	: R. Im. Hartono

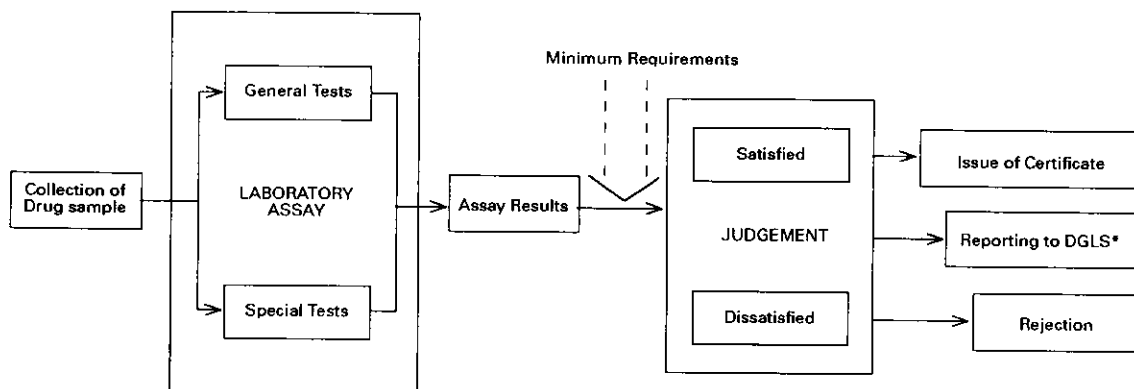
Technical Group of Veterinary Drug Assay Laboratory.

- | | |
|---------------------------------------|---------------------------------------|
| – Chief Antibiotic Production Section | : Diana Hermawati, D.V.M. |
| – Chief of General Medicement Section | : Unang Patriana, D.V.M. |
| – Chief of Pathology Section | : Endang Susanto, D.V.M. |
| – Chief of Viral Product Section | : Ida Lestari Soedijar, D.V.M., M.Sc. |
| – Chief of Bacterial Product Section | : Sumadi, D.V.M. |

STREAM OF CERTIFICATION TESTS

1. SAMPLING
 - a. At producers/importers
 - b. Check documents on production and condition of storage etc.
 - c. Direct transport to the Laboratory by cooling box.
2. GENERAL CHECK UP AT LABORATORY
 - a. Condition of package, container, attached documents, etc.
 - b. Volume, weight, color, and other characters.
 - c. Property, identity, moisture, quantity, etc.
3. SPECIAL LABORATORY TESTS
 - 1) BIOLOGICS
Safety, stability, potency, sterility, etc. including animal tests.
 - 2) ANTIBIOTICS
Potency, toxicity and other tests.
 - 3) GENERAL MEDICAMENTS
Qualitative and quantitative analysis, pyrogenicity, and other tests.
4. JUDGEMENT OF ASSAY RESULTS
Accumulating tests results and evaluate at the steering committee.
5. NOTIFICATION OF RESULTS
 - a. Issuing THE CERTIFICATE when satisfied.
 - b. Notification of REJECTION when failed.
 - c. Reporting the assay results to DGLS.

FLOW CHART OF QAULTY CERTIFICATION SYSTEM OF VETERINARY DRUGS AT VDAL



DGLS : Directorate General of Livestock Services

VETERINARY DRUGS TESTED FOR CERTIFICATION

Certification Test									
	86/87	87/88	88/89	89/90	90/91	91/92	92/93	93/94	94/95
1. Pharmaceutical and Premix	(113)	(36)	(134)	(112)	(167)	(224)	(242)	(250)	(214)*
1) Antibiotics	70	20	62	53	65	94	105	98	91
2) General Medicaments	43	16	72	59	102	130	137	152	123
2. Biologics	(40)	(25)	(48)	(39)	(55)	(113)	(108)	(98)	(92)*
1) Bacterials	2	9	16	15	17	45	34	26	12
2) Virals	38	16	32	24	38	68	74	72	80
T o t a l	153	61	182	151	222	337	350	348	306**

* Until March 13, 1995

** Plan for 1994/1995 is 319.

FINANCING

BUDGET OF THE GOVERNMENT OF INDONESIA

Budget appropriated for VDAL by the Government of Indonesia amounted to Rp. 1,629,039,000 for the period of 1983/1984 to 1988/1989. The budget have been spend on :

Preparation of the VDAL area, construction of a dormitory, staff houses, guard posts, an electric substation, fences, an acces road within the staff house area, puchase of assay instruments, reagents, office and running costs etc.

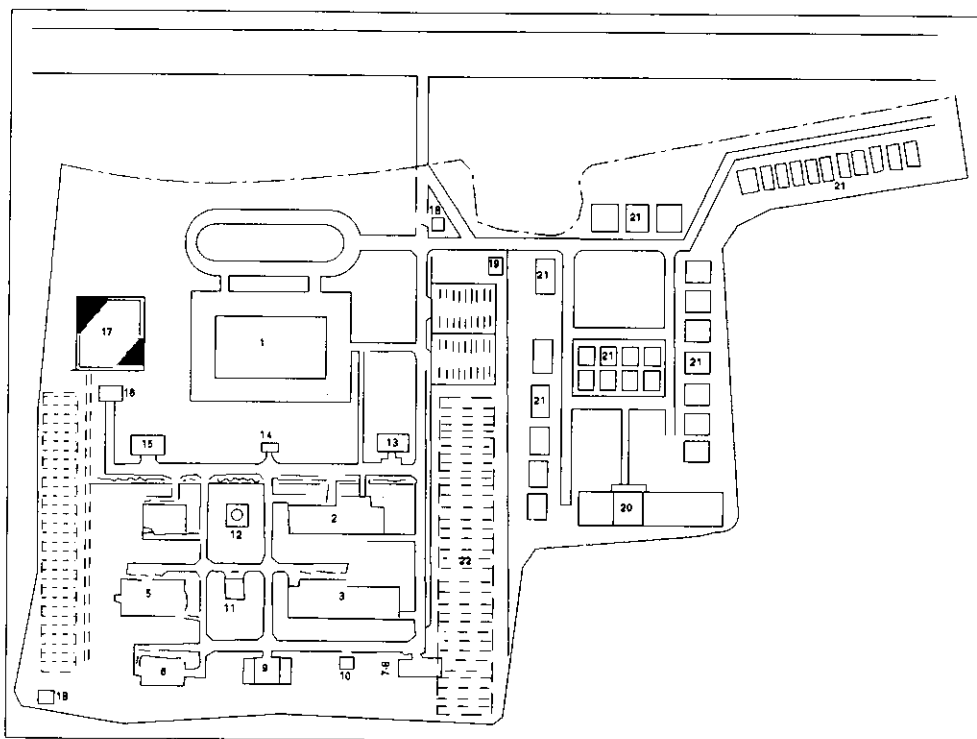
Budget appropriated for the VDAL for 1994/1995 fiscal year :

Development : Rp. 594,188,000

Routine : Rp. 588,080,000

Total : Rp. 1,182,268,000

BUILDINGS AND OTHER FACILITIES



Plane View of the Veterinary Drug Assay Laboratory

Legend :

1. Main building (Laboratories and Administrative Offices)	2,454 m ²
2. Experimental House of Mice and Guinea pigs	380 m ²
3. Experimental House of Chickens	494 m ²
4. SPF Chicken House	225 m ²
5. Breeding House of Mice and Guinea pigs	312 m ²
6. Breeding House of Conventional Chickens	337 m ²
7-8. Incinerator and Post-mortem House	96 m ²
9. Large and Midle-size Animal House	63 m ²
10. Explosive Storage	
11. Lavatory	
12. Elevated Water Tank	
13. Power House	
14. LPG Shed	
15. Workshop	
16. Water Treatment Tanks	
17. Drain Pool	
18. Guard Posts	
19. Electrical Sub-station	
20. Dormitory (Capacity of 22 inmates) :	530.10 m ²
21. Staff Houses (35 houses : B type = 1; C type = 5; D type = 19; E type = 10). Total floor Area	1,666.20 m ²
22. Fodder Fields	

ASSISTANCE OF THE GOVERNMENT OF JAPAN

1. Grant Capital Aid

The main building, animal house and other related facilities of VDAL were constructed with the grant capital aid of the Government of Japan. Major equipment such as a generator, an incinerator and a water purifier etc. were also provided by the grant capital aid.

The construction of VDAL buildings started in March 1984 and was completed in January 1985. The turn over ceremony of VDAL was held in the presence of Directory General of Livestock Services on 26th January 1985.

The grant capital aid totalled 960 million yen or 4.3 billion rupiah at the then value.

2. Technical Cooperation

Technical cooperation has been introduced since April 1984 in addition to the grant capital aid and will be terminated on March 1989 as the First Five (5) years programme, but it is expected to be extended for Two (2) more years until March 1991. Technical cooperation consists of three main components, that is to say, dispatch of Japanese experts, equipment provision and technical training of counterparts in Japan. Recently it is extended for Two (2) more years as after care program until June 1996.

1) Dispatct of experts

Long-term and short-term experts of various specialities are planned to be assigned in the course of the cooperation term. They are: chief advisor, coordinator (liaison officer), experts on bacteriology, virology, antibiotics, pathology and laboratory animal etc.

Assignment of Japanese experts (as of March 1991).

Assignment	1984/85	1985/86	1986/87	1987/88	1988/89	1989/90	1990/91
Long-Term Expert	2	6	8	7	4	4	2
Short-Term Expert	3	5	11	10	11	6	3
Total	5	11	19	17	15	10	5

2) Equipment provision

Equipment are to be provided for VDAL each year in accordance with the progress of the project. The total amount of the machinery and equipment granted has the value of 459 million Yen from the beginning of the project up to the end of fiscal year 1990/91. In aftercare programme it has the additional value of 60 million Yen.

3) Technical Training of Counterparts in Japan

Indonesian officials with VDAL are expected to study in Japan every year until the technical cooperation terminates. They study at the National veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries and other related institutions. Officials who study on laboratory animals train at the Kobuchizawa Laboratory Animal Breeding Farm, the Nippon Institute for Biological Science. The technical training includes observation tours to various institution concerned. A Master Course or further study at Japanese University is also programmed as a part counterpart training in Japan. Thirty six (36) officials have so far completed counterpart training in Japan and six (6) officials are taking further study at Japanese University as of March 1995.

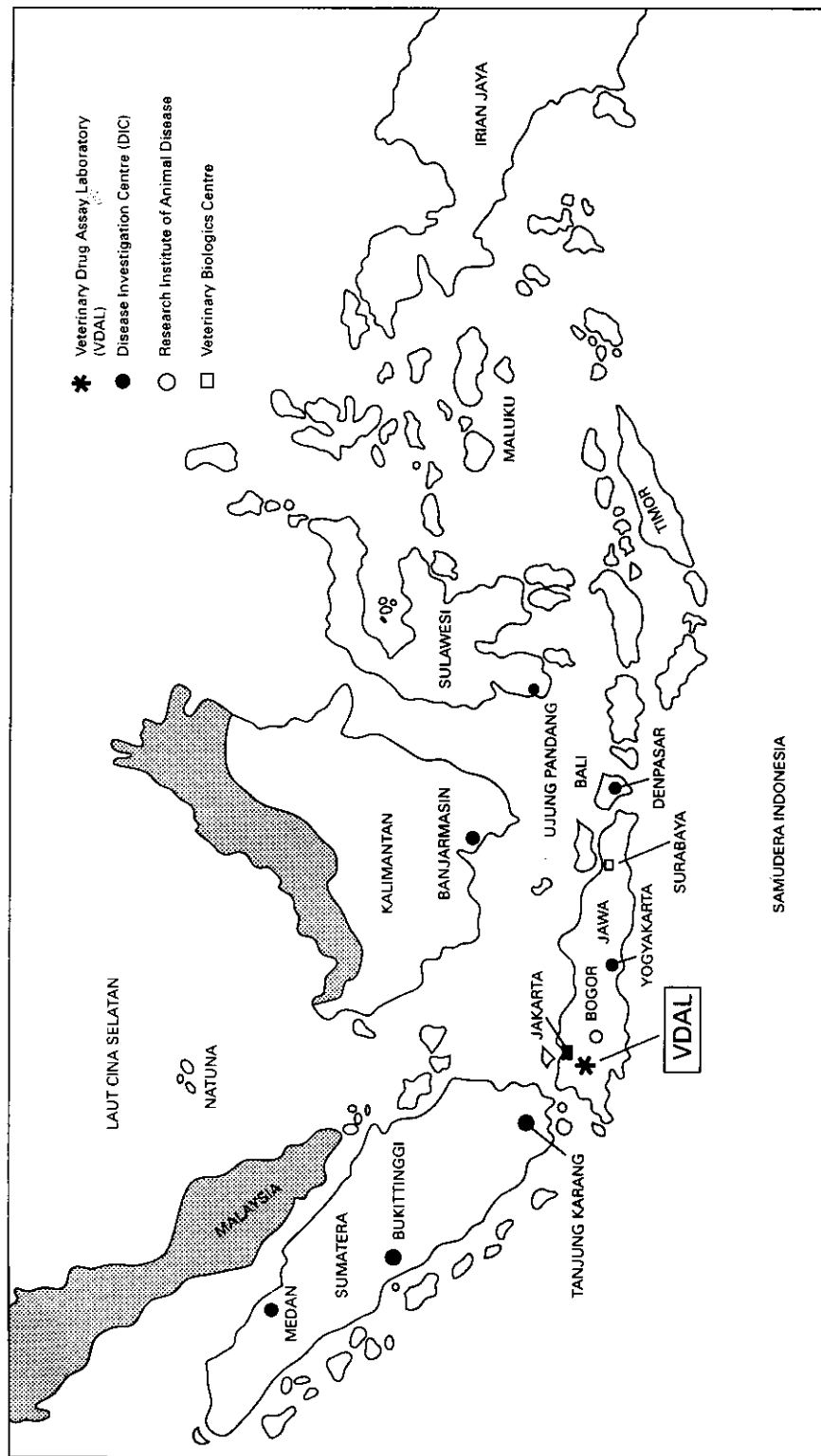
4) Seminar/Training Course

In order to achieve sound development of Veterinary Drug Control in Indonesia which is a main purpose of the project itself, a group training course for Veterinary Drug Inspectors is conducted yearly at VDAL since 1987/1988 until 1990/1991 fiscal year.

Ninety five (95) Veterinary Officers from Provinces, including technical staff of Disease Investigation Centres, Provincial Veterinary Laboratory (B and C type Laboratories) staff and PUSVETMA, have participated in the past (4) years courses.

Other training course which had been conducted at VDAL :

- FAO/APHCA workshop on Registration, certification and quality control of Veterinary Biologic for Asean Countries, 1990/1991.
- The First International Training Course on Veterinary Drug Improvement, for Asean and Pacific Countries, 1992.
- The Second International Training Course on Veterinary Drug Improvement, for Asean and Pacific countries, 1993.
- The Third International Training Course on Veterinary Drug Improvement, for Asean and Pacific countries, 1994.
- Training Course of Veterinary Drug Company Technical Staff I 1994.
- Training Course of Veterinary Drug Company Technical Staff II 1995.



LOCATION MAP OF VETERINARY DRUG ASSAY LABORATORY AND OTHER RELATED INSTITUTIONS

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