DRUG ADMINISTRATIONOF VIETNAM

DRUG QUALITY MANAGEMENT DIVISION

PROCEDURE FOR HANDLING AND RECALLING VACCINES AND BIOLOGICALS VIOLATING QUALITY STANDARDS

Code: QT.CL.11.02

	Prepared by	**Checked by**	**Approved by**
Full name	Đỗ Thu Hương	Nguyễn Văn Viên	Trương Quốc Cường
Signature			

1. *All concerned personnel must study and comply with the content of this procedure.*
2. *The content of this procedure shall be treated as the direction of the Director-General of the Drug Administration of Vietnam.*
3. *Each office is provided with one copy of this procedure (with an official stamp). If more than one copy is needed, requests must be made to the ISO secretary in order for them to be stamped. An electronic version is available on the Intranet for sharing purposes.*

RECIPIENT *(Full name and tick an X in the box)*

☐	DAV management board	☐	Drug registration dept.
☐	ISO committee	☐	Drug quality management dept.
☐	Oficial Administration dept.	☐	Drug price control dept.
☐	Pharm. Legislation & international Integration dept.	☐	Drug information and advertising dept.
☐	Planning & financial dept.	☐	Cosmetic management dept.
☐	Drug business management dept.	☐	Inspection dept.
☐	NRA committee	☐	Training Center
☐	Drug and Cosmetic magazine	☐	

REVISIONS

Rev.	Date	Position	Revised content	Note
02	15/01/2014	Section 5.2.4.2, d)	Addition of procedure for handling vaccine & biologicals failed on release	
		-	Update according to document management procedure	
03	10/06/2015	Sec.5.2.4.2	d) Add the handling/monitoring for vaccine-used person.	
			f) Add the handling to the voluntary recall	
		Sec.5.2.	Add the Sec.5.2.7. Review recall report, evaluation of effectiveness of recall actions and supplemental actions	
			Change the previous Sec.5.2.7 to Sec.5.2.8	
		BM.CL.11.03/01 BM.CL.11.03/01	Add the requirement to the manufacturer/importer to take the monitoring of health condition of people who received these violated lots	

1. PURPOSE

This stepwise description is to ensure that all dealings with offences follow the same standard procedure.

- To ensure that all defective vaccine and biological product of different manufacturers, importers, exporters or traders are dealt with in an efficient manner, following the same method;

- To ensure that all steps are complied with the instructions stipulated in the Circular on drug quality control and with current pharmacy regulations;

- To ensure that all staff dealing with defective vaccines and biologicals follow an approved procedure;

- To ensure that changes can be made when a new procedure is developed.

2. SCOPE

This procedure is applied for dealings with defective vaccines and biologicals , which are being circulated across Vietnam, based on the test results issued by the National Institute for Control of Vaccines and Biologicals (NICVB).

This procedure also provides a frameworkto deal with information about defective vaccines and biologicals from other Government Agencies, organizations, and individuals.

3. REFERENCES

- The Law on Pharmacy in 2005;

- The Panel Code in 1999;

- The Intellectual Property Law in 2005;

- The Law on Quality and Products in 2007;

- The Government Decree No. 79/2006/NĐ-CP dated 09/8/2006 specifying several articles of the Law on Pharmacy, and the Government Decree No. 89/2012/NĐ-CP dated 24/10/2012on amendments and supplements to the Decree No. 79/2006/NĐ-CP;

- The Government Decree No. 132/2008/NĐ-CP dated 31/12/2008 specifying the implementation of some articles of the Law on product and goods quality;

- The Government Decree No. 93/20011/NĐ-CP dated 18/10/20011, regulating administrative penalties for drugs, cosmetics and medical equipments;

- The Circular No. 09/2010/TT-BYT dated 28/4/2010 issued by the Ministry of Health instructing drug quality control;

- The Circular No. 04/2010/TT-BYT dated 12/02/2010 issued by the Ministry of Health instructing taking drug samples for testing;

- The Circular No. 44/2014/TT-BYT dated 25/11/2014 issued by the Ministry of Health regulating drug registration;

- The Circular No. 04/2008/TT-BYT dated 20/5/2008 issued by the Ministry of Health instructing drug labeling.

4. DEFINITIONS AND ABBREVIATIONS

4.1. Terminologies

Defective Vaccines and biologicals: refer to vaccines and biologicals that did not meet the quality standards which have been registered with the competent authority.

Vaccines and biologicals businesses: refer to the manufacturing, importing, exporting, wholesaling, retailing, storage services and quality control of drugs (vaccines and biologicals).

Category 1 units : warehouse of manufacturers, importers/exporters, wholesaler companies, warehouse of provincial center for preventive medicine, warehouse of pharmacy department of central or provincial hospitals, of private hospitals and provincial specialized health care center.

Category 2 units: the pharmacy department of district hospitals, immunization points at health care centrer and private health practices.

4.2. Abbreviations

- DAV: Drug Administration of Vietnam
- DDQC: Division of Drug Quality Control
- NICVB: National Institute for Control of Vaccines and Biologicals;
- GDPM: General Department for Preventive Medicine
- MoH: Ministry of Health;
- GMP: Good Manufacturing Practice;
- QT.CL.11…: Procedure for dealing with drugs violating quality standards

5. PROCEDURE

5.1.Procedure for handling defective vaccines and biologicals

Responsibility	Dealing process	Description/Forms
	Information	
DAV admin DDQC admin	Reception	5.2.1
Head of DDQC	Task assignment	5.2.2
DDQC staff	Document review	5.2.3
DDQC staff	Proposal of measures	5.2.4 BM.QLD.47.01 BM.QLD.47.02 BM.QLD.47.03
DDQC management	Review	5.2.5
DAV Directors	Approval	5.2.6
DDQC staff	Evaluation	5.2.7
DAV Admin Specialist	Document filing and monitoring	5.2.8

5.2.Description of the procedure diagram

5.2.1.Information reception

- Information documents about the defective products is received by the DAV reception unit, which may come from: relevant Government authorities (police, customs, market control agency, etc…); the National Institute for Control of Vaccines and Biologicals, Central national for drug quality controls, Provincial Health Services or Provincial Drug Quality Control Laboratories, foreign drug regulatory authorities, pharmaceutical companies, other organizations (mass media, etc...), and consumers.

- DAV reception staff records those information into administrative book– information must be recorded completely

- DDQC reception staff, after receiving the document from DAV reception units, should registes this documents in DDQC information reception book (signatures confirming the transaction of the information between DAV and DDQC staff are required)

- Information received via emails or other electronic channels shall be reported to the DAV leader for direction and forwarded to DDQC for follow-up actions. DAV reception staff registes the information in the reception book.

5.2.2.Task assignment

- DDQC reception staff presents the document to DDQC Head.
- DDQC Head review the document and then assigns staff to process.
- DDQC reception staff get back the documents, then forward them to the staff in charge. The staff signs to confirm of the reception.

* Processing time: same day as reception of information from DAV admin.

5.2.3.Information review

The responsible staff checks the information and its legality:

a) If the defect of product is confirmed and all eligible information is sufficient (i.e. there is sufficien of legal information), it will be moved to step 5.2.4:

- Availability of Certificate of analysis of defective product that is provided by NICVB; or the inspection minutes/report issued by an MoH or DAV inspection team, or by related regulatory authorities, or reports of the manufacturer, importer or authorized importers.

- Availability of sampling minutes of the defective products.

b) In case, additional information is needed or the validity of the information is not confirmed, for example:

- Absence of the sampling minutes

- The certifcate of analysis do not show the precise defective level.

The staff in charge should collect further information (by phone, email, written requests, etc...)

- If additional information confirms the violation, it will move to 5.2.4

- If additional information still does not confirm the violation (i.e. available information does not form sufficient legal basis for decision to be made), the staff in charge drafts a recall letter according to the instructions specified in section d) or f) in 5.2.4.2 below, and then sends it to the DDQC Head (to 5.2.5)

5.2.4. Handling

Based on the defective product document and on the following defective classification criteria, the staff on charge drafts the recall letter in using the form attached to this SOP.

5.2.4.1. Levels of violation

a) Level 1: Defective products which could cause serious health problems or death.

- Quality defective products:

+ Products that contains wrong concentration/content of active ingredient which could cause serious health problems;

+ Products that contains wrong active ingredients which could cause serious health problems;

+ Unregistered products, which could cause serious health problems (e.g.steriled products manufactured by unlicensed businesses);

+ Products do not meet general safety requirements (toxicity).

+ Injectable products that do not meet the specification on sterilization, pyrogen or endotoxin criteria.

+ Products that is recall urgently by foreign drug regulatory authorities (for imported products).

+ Unsafe products

+ Products that their composition concentration is exceed the limit, which could pose serious health hazards (e.g. high toxic ingredients; narrow therapeutic window).

- Product that contain the hight toxic ingredient or narrow therapeutic window ingredient or is non-venous injectable drugs, is labelled with incorrect information about concentration or administration routes, or dosages

b) Level 2: Defective products may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote

- Quality Defective Drugs:

+ Product does not meet requirement on potency criteria.

+ Products of that the content of component does not conform with specification (except for those at level 1).

+ Products that contains wrong ingredients (except for those at level 1).

+ Oral product does not meet the criteria on sterilisation.

+ Clarity, relative contaminants, particulate matter of injectable products is failed.

+ Multidose injectable fluid contains less than 75% of the nominal volume.

+ Multidose powder for injection contains less than 75% o of the labelled mass.

+ pH of injectable drugs.

+ Sedimentation rate of injectable suspensions or emulsions.

- Products that are recalled by foreign drug regulatory authorites, except for those are urgently recalled and proved to be imported in Vietnam.

- The following cases, except those are under urgent recalls regulated in level 1:

+ Confusion products during the labelling or secondary packaging; products labeled with incorrect information about administration routes, dosages or indication;

+ Products that do not have a registration number or licence to be imported;

+ Products that are manufactured or imported which do not match with the registration and importation documents;

+ Products that the content or concentration of one or more components is exeed the permitted limit;

+ Products that contain substandard ingredients or unknown origin ingredients (e.g.: illegally imported ingredients, ingredients supplied by

manufacturers who do not have pharmaceutical business licence, or ingredients that are not intended for use by humans);

- Products that are not stored properly;
- Expired products.

c) Level 3: Violative product is not likely to cause any adverse health consequences

- Quality defective products:

+ Weight variation for multidose powder for injection is not conformed, but the everage mass is higher than 75% of labeled amount.

+ Volume for multidose injectable fluids is not conformed, but is higher than 75% of nominal volume declared on label.

+ Moisture of powder for injection is out of specification

+ pH of orally administered products is out of specification

- Violations of regulations (change of primary packages, labelling …).
- Products that do not meet requirements on the labelling, except for what stated in levels 1 or 2.
- Products of which the packaging does not meet requirements.

5.2.4.2. Recall notification

The staff in charge prepare a recall notification as instructed below:

a) For level 1: urgent recall

DAV issues notifications for urgent recalls to GDPM, all provincial health services, to manufacturers or importers, ministerial or sectoral health services, MoH Inspectorate, Department of Therapy, National Immunization Program, and various DAV divisions. The notifications are also announced on mass media so that end users are informed of the defective drugs and return them to the suppliers.

Recall form for level 1: BM.CL.11.03/01

*Processing time: the same day of receving the information.

b) For level 2

- Apply to the product violated at level 2 and;

+ Samples are taken at manufacturers or at the etablisment of Category 1 units by NICVB or by regional Pasteur Institutes or by provincial center for

preventive medicine or by other drug agencies. The test results are confirmed by the NICVB.

+ Or samples taken at Category 2 units and the fail criteria is assessed that is production defect.

- Apply to the products that are recalled by the foreign regulatory authorities for violating quality standards or GMP.

DAV issues notifications to GDPM, Provincial Health Services, manufacturers or importers; National Immunization Program (if products supplied by the Program), sectoral health departments, MoH Inspectorate, and various DAV divisions.

Recall form for level 2: BM.CL.11.03/02

* Processing time: within 10 days from date of receving the information.

b) For level 3

- Product violated at level 3;

- Samples are taken at manufacturers or at the etablisment of Category 1 units by NICVB or by regional Pasteur Institutes, or by provincial center for preventive medicine or by other drug agencies. The test results are confirmed by the NICVB.

DAV issues notifications to manufacturers or importers, GDPM and to Provincieal Health Services for enforcement.

Recall form for level 3: BM.CL.11.03/03

* Processing time: within 10 days from reception of notification from DAV admin.

d) Handling the specific cases:

- If the vaccine or biological were failed during lot release procedure in NICVB, DAV/DDQC should assesse the defective level according the instruction in 5.2.4.1 and:

- For domestic products, DAV issues the waring letter to manufacturer to request that:

- In case substandard product: Destroys and submits report to DAV.
- In case of violation of labels or secondary packaging: Manufacturer may destroys or corrects the defective product, make the report to DAV.

- For imported products, DAV could issue the warning letter to the importer to destroy or send back the violated product.

+ For domestic manufacturer, which has violated product at level 1, 2; or at least 2 lots of product violated at level 3, a spot inspection should be carried out to investigate the causes and DAV may take a addtional actions.

- For cases where inspectional and managerial authorities identify that storages do not meet regulations and determine that cold chains do not meet the requirements, recalls will be initiated according to cold chains starting from immediate wholesalers from cold chains identified.

- For complications: Review the report of users, if the complications happen at 2 or more of vaccination facilities or there appear numerous cases of complication, or there are serious complication: DAV should issue the notifications to provincial health departments to temporarily stop using the products, and to review all the cold chains and use conditions, and make the detail reports to DAV and GDPM. DAV should work with GDPM to report to the MoH Council for Post-Vaccination Complication Management; in the meantime. DAV should request the NICVB to take the sample/re-test the samples. DAV will take the actions accordingly to the opinion of Council and the re-test results..

- Additional action for monitoring the vaccinated person: in recall notification, DAV would request the manufacturer/importer/distributor, in coordination with the provincial health services and vaccination facilities to monitoring the vaccinated person, handling the complications and making the AEFI reports to DAV and GPDM.

* Processing time: no longer than 10 working days.

e) Special offences:

- Request to stop the distribution and to recall all products in following cases:

+ Violation of quality at level 1.

+ Products have 02 batches violating quality standards which happened during the effective time of registration number.

- Request to stop the distribution and to recall certain/some batches of products that is manufactured in a certain period of time, at which the manufacturer is not complied with GMP ; and which are confirmed to be defective products or to cause harmful reactions.

f) For voluntary recall:

After receiving the report of manufacturers, the staff in charge shall analyze all available information to determine the recall level and compose the

response letter to manufacturer. In case of level-1 violation, the DAV shall issue the urgent notice.

Notes: For special cases, depending on the defect, the DAV management determines reporting timeframe.

The staff in charge drafts the notification and sends to DDQC management for review.

5.2.5.Review of the DDQC Head

Division Head reviews the notification draft:

- If s/he does not agree with its content, s/he will send it back to the processing staff to revise as per 5.2.4

- If otherwise, s/he will initial the notification

DDQC admin presents the notification draft and other relevant documents to the DAV management.

*Processing time: within 24 hours.

5.2.6. Approval of the DAV management

DAV Director reviews the notification draft:

- If s/he does not agree with its content, it will be sent back to step 5.2.5
- If s/he agrees with its content, s/he will sign and send it to the DAV admin.

5.2.7. Review recall report, evaluation of effectiveness of recall actions and supplemental actions

a) Staff in charge should monioring the recall process, review the recall report and assess the effectiveness of recall action:

+ review the date and method of notifying of the recall.

+ review the list/number of establishments or persons to whom the defective product has been supplied, number of establishment that have received the recall letter, and that have response or have returned the recall drug.

+ review the quantity in stock, quantity of drug that is returned from distributors, the rate of returned drug.

+ review the self–assessement of effectiveness of recall action. The effectiveness of recall action should be evaluated in considering the date that the drug was distributed, circulated on market, the date of recall completion, the risk to patient‘s health and ADR reports.

+ review the investigation result; assess the risk to other lot of violated product and/or other products which were manufactured in the same conditions .

+ conclusion on recall result

b) Base on the above analysis, in case the recall process is not effective, by that the violated product may still available on market and may pose the risk to user health, Drug quality management division propose to DAV leaders to :

+ Inspect the record of recall process; in some case DAV or Provincial Healt Service may contact a percentage of customer s in distribution list to check the effectiveness of recall action.

+ Request to re-issue the recall letter, re-continue the recall action and submit additional report.

+ Request the additional report on remaining the produttion conditions

+ Take the specific inpection on the manufacturer or importer.

+ Take the additional supervision on the quality of product in a certain period.

5.2.8. Filing of documents and following up with recalling reports

DDQC reception staff is responsible for:

- Filling the documents, following up with the issuance of the notification of the DAV reception unit, making sure DAV regulations on sending and receiving documents are complied with.
- Registering the drugs in the list of defective product.

The staff who is responsible for supervising the recall of drugs assesses the recall reports to initiate timely actions.

5. DOCUMENTATIONS

Notifications of substandard quality products, testing results issued by NICVB, minutes for taking samples, or inspection minutes issued by inspection teams or QC staff, and other documents (if any) are all filed at the DDQC and DAV - Annual documentation.

7. ATTACHED FORMS

- BM.QLD.47.01: Notification for recalls level 1;
- BM.QLD.47.02: Notification for recalls level 2;
- BM.QLD.47.03: Notification for recalls level 3;
- BM.QLD.47.04: Notification to provincial health departments regarding drug recalls.

BM.CL.11.02/01

MINISTRY OF HEALTH

DRUG ADMINISTRATION OF VIETNAM

SOCIALIST REPUBLIC OF VIETNAM

Independence – Freedom - Happiness

No.:...../QLD – CL
Termination of circulation
of substandard quality products

Hà Nội, date month year

URGEN

To: - Health department of provinces/cities attached to Central Government
- Enterprise…….
- Mass media (Television, radio, newspapers…)

- Pursuant to current regulations in the Pharmacy of Vietnam
- According to Notification No. …./..... dated .../.../200… issued by ...., accompanied by test results report No. ..... dated.../.../200…for ..... (name of product), Batch number .....; Expiry date: ....., Registration No. .....; manufactured by ….....;or imported by .....Official product samples taken at ……..... The product fails to meet quality standards in ……..

The DAV requests:

1. an urgent termination on the nation-wide scope of the circulation of ..... (product), Batch No:.....; Expiry date: ....., Registration No. ....., and manufactured by ….....

2. a cooperation between the manufacturer and the supplier (or the importer and the supplier) to:

+ send an urgent notification to retailers and users of the product: ……., Batch No: .....; Expiry date: ....., Registration No. ....., and manufactured by ….....and urgently recall the whole batch which do not satisfy quality standards as stated above.

+ issue an urgent report on the manufacture, importation and distribution of the recalled products to the DAV.

+ submit recall reports and documents as regulated in the Circular No. 09/2010/TT-BYT dated 28/4/2010 issued by the Ministry of Health instructing the drug quality control to the DAV by ……(date).

3. that health departments of provinces and cities attached to the Central Government and sectoral health departments urgently notify retailers and pharmacies to recall the subquality product as stated above, monitor the recalls, take actions on those committing offences according to effective requirements, and to report to the DAV and other related authorities.

+ Cooperate with vaccination facillities to strictly monitor health condition of people who received these violated lots, report to authorized agency

for promptly action ; recall immediately other lots of violated product if admit any sign of violation on quality or safety.

4. that the mass media (television, radio, newspapers …)publicize the recall notification and request consumers to stop using the recalled products and to return them to the supplier.

5. that provincial health departments where the manufacturers or importers base or where the samples are taken take actions against the offences according to current regulations./.

Recipients:
- As above;
- General department of Preventive medicine, Health Inspectorate, Department of Therapy (to collaborate);
- The NIDQC, HCMC IDQC;
- Department of Health (Ministry of Defence);
- Department of Health (Ministry Public Security);
- Department of Health (Ministry of Transport);
- Division of Drug Registration, Division of Pharmaceutical Business Management, Division of Drug Communication and Advertising (DAV);
- Sampling agencies (to undertake);
- MoH & DAV websites; Pharmacy and Cosmetics Magazine;
- NRA office;
- Filing: Admin, CL (02 copies).

DIRECTOR-GENERAL

Trương Quốc Cường

BM.CL.11.02/02

MINISTRY OF HEALTH

DRUG ADMINISTRATION OF VIETNAM

SOCIALIST REPUBLIC OF VIETNAM

Independence – Freedom - Happiness

No.:...../QLD – CL
Termination of circulation
of substandard quality products

Hà Nội, date month year

To: - Provincial Heathl Services
- Enterprise…….

- Pursuant to current regulations in the Pharmacy of Vietnam
- According to Notification No. …./..... dated .../.../200… issued by ...., accompanied by test results report No. ..... dated.../.../200…for ..... (name of product), Batch number .....; Expiry date: ....., Registration No. .....; manufactured by ….....;or imported by ..... Official product samples taken at ……..... The product fails to meet quality standards in ……..

The DAV requests:

1. a termination on the nation-wide scope of the circulation of ..... (product), Batch No:.....; Expiry date: ....., Registration No. ....., and manufactured by ….....

2. a cooperation between the manufacturer and the supplier (or the importer and the supplier) to:

+ send a notification to retailers and users of the product: ……., Batch No: .....; Expiry date: ....., Registration No. ....., and manufactured by ….....and recall the whole batch which do not satisfy quality standards as stated above.

+ issue a report on the manufacture, importation and distribution of the recalled products to the DAV.

+ submit recall reports and documents as regulated in the Circular No. 09/2010/TT-BYT dated 28/4/2010 issued by the Ministry of Health instructing the drug quality control to the DAV by …… (date).

+ Cooperate with vaccination facillities to strictly monitor health condition of people who received these violated lots, report to authorized agency for promptly action ; recall immediately other lots of violated product if admit any sign of violation on quality or safety.

3. that health departments of provinces and cities attached to the Central Government and sectoral health departments notify retailers and pharmacies to recall the subquality products as stated above, monitor the recalls, take actions on those committing offences according to effective requirements, and to report to the DAV and other related authorities.

4. that provincial health departments where the manufacturers or importers base or where the samples are taken take actions against the offences according to current regulations./.

Recipients:
- As above;
- General department of Preventive medicine, Health Inspectorate, Department of Therapy (to collaborate);
- The NIDQC, HCMC IDQC;
- Department of Health (Ministry of Defence);
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- Division of Drug Registration, Division of Pharmaceutical Business Management, Division of Drug Communication and Advertising (DAV);
- Sampling agencies (to undertake);
- MoH & DAV websites; Pharmacy and Cosmetics Magazine;
- NRA office;
- Filing: Admin, CL (02 copies).

DIRECTOR-GENERAL

Trương Quốc Cường

BM.CL.11.02/04

MINISTRY OF HEALTH
DRUG ADMINISTRATION OF VIETNAM

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom - Happiness

No.:...../QLD - CL *Hà Nội, date month year*

Termination of circulation
of substandard quality products

To: - Provincial Health Services
- Manufacturers/Importers …….

- Pursuant to current regulations in the Pharmacy of Vietnam
- According to Notification No. …./..... dated .../.../200… issued by ...., accompanied by test results report No. ..... dated .../.../200… for ..... (name of product), Batch number .....; Expiry date: ....., Registration No. .....; manufactured by ….....; or imported by ..... Official product samples taken at ……..... The product fails to meet quality standards in ……..

The DAV requests:

1. a termination of the circulation of ..... (product), Batch No:.....; Expiry date: ....., Registration No. ....., and manufactured by ….....

2. a cooperation between the manufacturer and the supplier (or the importer and the supplier) to:

+ send a notification to retailers and users of the product: ……., Batch No: .....; Expiry date: ....., Registration No. ....., and manufactured by ….....and recall the whole batch which do not satisfy quality standards as stated above.

+ submit recall reports and documents as regulated in the Circular No. 09/2010/TT-BYT dated 28/4/2010 issued by the Ministry of Health instructing the drug quality control to the DAV by …… (date).

3. that provincial health departments where the manufacturers or importers base or where the samples are taken take actions against the offences according to current regulations./.

Recipients:
- As above;
- General department of Preventive medicine, Health Inspectorate, Department of Therapy (to collaborate);
- The NIDQC, HCMC IDQC;
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- NRA office
- Filing: Admin, CL (02 copies).

DIRECTOR-GENERAL

Trương Quốc Cường

BM.CL.11.02/04

MINISTRY OF HEALTH
DRUG ADMINISTRATION OF VIETNAM

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom - Happiness

No.:...../QLD - CL *Hà Nội, date month year*
Ref:

To: - …..provincial Health Service
- Institute:
- Enterprise:

The DAV received the request No.:..... dated ..... accompanied by test results report No. ..... dated .../.../200… for ..... (name of product), Batch number .....; Expiry date: ....., Registration No. .....; manufactured by ….....; Official product samples taken at ……..... The product fails to meet quality standards in …….. In response to the request, the DAV requests

1. that the Health Department of ..... (province) take actions against the circulation of..... (product), Batch No:.....; Expiry date: ....., Registration No. ....., and manufactured by …..... in the province according to current regulations, and take actions against the offences.

2. that the Enterprise .....:

-audit the whole manufacturing process, material and package quality to ensure the products meet the quality standards till the expiry date.

-take samples of (product) ....., batch No.: ....., expiry: ..... (both those in the storage and being marketed), send the samples together with the minute for taking the samples to a Government QC authorities to assess the quality of the products, and recall the whole batch if found violating quality standards.

- report to the DAV by (date): .....

3. thatInstitute ..... take samples to assess the quality of the (product) ..... manufactured by .....; that attention is paid to the batch No.: ..... as stated above.; and that Intitute report the results to the DAV.

Recipients:
- As above;
- General department of Preventive medicine;
- NRA office;
- Filing: Admin, CL (02 copies).

DIRECTOR-GENERAL

Trương Quốc Cường