



Kementerian Kesihatan, Brunei Darussalam  
Ministry of Health, Brunei Darussalam

For office use only

Date received:

Ref: MPQ/PVS/

**BORANG LAPORAN KUALITI PRODUK UBAT / MEDICINAL PRODUCT QUALITY REPORTING FORM**

**(1) MAKLUMAT PRODUK UBAT / MEDICINAL PRODUCT DETAILS**

\*Nama produk pada label / Name of product on label: \_\_\_\_\_

Bahan aktif / Active ingredient: \_\_\_\_\_ Pengilang / Manufacturer: \_\_\_\_\_

Saiz pak asal / Original pack size: \_\_\_\_\_ Jumlah produk terjejas / Quantity of product affected: \_\_\_\_\_

\*Bac / Batch number: \_\_\_\_\_ Tarikh mansuh / Expiry date: \_\_\_\_\_

**(2) BUTIRAN LAPORAN KUALITI / QUALITY REPORT DESCRIPTION**

\*Tarikh isu kualiti dikesan/ Date quality issue was detected: \_\_\_\_\_

\*Sila beri penerangan ringkas berkaitan isu yang dilaporkan / Please provide brief description about the reported issue:

**(3) KETERANGAN LANJUT MENGENAI PRODUK UBAT / ADDITIONAL INFORMATION ON MEDICINAL PRODUCT**

Adakah seal pada produk sudah dibuka semasa menerima stok?  Ya / Yes  Tidak/ No  Produk tidak mempunyai seal / Product has no seal  
Was the seal on product broken when you received the stock?

Adakah stok produk dengan bac yang sama diperiksa?  Ya / Yes  Tidak/ No  
Were other stocks of the same batch examined?

Jika ya, apa keadaan produk tersebut?/ If yes, what is the product condition?  
\_\_\_\_\_

Adakah stok bac yang berlainan juga diperiksa?  Ya / Yes  Tidak/ No  Tidak ada bac lain / No other batches available  
Were stocks of a different batch also examined?

Jika ya, apa keadaan produk tersebut?/ If yes, what is the product condition?  
\_\_\_\_\_

Kondisi penyimpanan produk/ Storage conditions of product:

Suhu bilik/ Room temperature ( $\leq 25^{\circ}\text{C}$ )

Suhu rangkaian sejuk/ Cold-chain temperature ( $2^{\circ}\text{C}- 8^{\circ}\text{C}$ )

Kelembapan/ Humidity ( $\leq 60\%$  relative humidity)

Lain-lain/ Others \_\_\_\_\_

Sampel produk dihantar untuk siasatan lanjut?  Ya / Yes  Tidak/ No  
Product sample submitted for further investigation?

(Nota: Jika produk adalah menggunakan rangkaian sejuk- sampel akan dikuarantin di peti sejuk di tempat ianya dikesan /Note: If cold chain product- sample are to be quarantined at the refrigerator at the detected site)

**(4) MAKLUMAT PELAPOR / REPORTER DETAILS**

\*Nama pelapor / Reporter's name: \_\_\_\_\_

Jawatan / Post: \_\_\_\_\_ \*Tempat bertugas / Place of work: \_\_\_\_\_

\*No. telefon / Tel. no.: \_\_\_\_\_ E-mel / E-mail: \_\_\_\_\_

Tandatangan & cop rasmi /

Signature & official cop: \_\_\_\_\_ Tarikh laporan/ Date of reporting: \_\_\_\_\_

Untuk diisi jika pelapor adalah bukan yang mendapati isu kualiti produk  
To be filled only if reporter did not find the product quality issue

Nama kakitangan / Name of staff: \_\_\_\_\_

Jawatan / Post: \_\_\_\_\_ Tempat bertugas / Place of work: \_\_\_\_\_

No. telefon / Tel. no.: \_\_\_\_\_ E-mel / E-mail: \_\_\_\_\_

Tarikh dilaporkan kepada pelapor / Date reported to reporter: \_\_\_\_\_

**(5) UNTUK KEGUNAAN FARMASI / FOR PHARMACY USE**

Nama kakitangan in-čaj / Name of staff in charge: \_\_\_\_\_

Jawatan / Post: \_\_\_\_\_ Tempat bertugas / Place of work: \_\_\_\_\_

No. telefon / Tel. no.: \_\_\_\_\_ E-mel / E-mail: \_\_\_\_\_

Tarikh menerima laporan dan sampel / Date received report and sample: \_\_\_\_\_

Tandatangan & cop rasmi /

Signature & official cop: \_\_\_\_\_

**PANDUAN MELAPOR KUALITI PRODUK UBAT  
GUIDANCE ON REPORTING MEDICINAL PRODUCT QUALITY**

**APAKAH YANG PERLU DILAPORKAN?  
WHAT TO REPORT?**

Sila laporkan jika awda mengesyaki mengenai kualiti produk ubat. Bagi melapor reaksi ubat adwers/ kejadian adwers berikutan immunisasi, sila gunakan borang *Suspected Adverse Drug Reaction Reporting Form/ Adverse Event Following Immunisation Reporting Form*.

*Please report if you have any suspicion regarding the quality of the medicinal product. For adverse drug reaction reporting/ adverse event following immunisation reporting, please use Suspected Adverse Drug Reaction Reporting Form/ Adverse Event Following Immunisation Reporting Form.*

**BAGAIMANA CARA MELAPORKAN?  
HOW TO REPORT?**

Dapatkan borang ini dari farmasi kerajaan yang berdekatan (hospital/ pusat kesihatan). Sila isikan borang ini selengkap mungkin. **Butiran bertanda (\*) adalah WAJIB DIISI.** Setelah lengkap diisi, sila pulangkan borang ini dan sampel produk (jika ada) ke farmasi kerajaan yang berdekatan (hospital/ pusat kesihatan), atau awda boleh e-mel kepada kami. Sila berikan maklumat perhubungan awda untuk membolehkan kami menghubungi awda sekiranya maklumat yang lebih lanjut mengenai laporan awda diperlukan.

*This form can be obtained from the nearest government pharmacy (hospital/ health centre). Please fill in the form as completely as possible. **Particulars marked with (\*) are MANDATORY.** Once completed, please return the form and the product sample (if available) to the nearest government pharmacy (hospital/ health centre), or email directly to us. Please provide your contact details as well to allow us to obtain further information about your report if necessary.*

FOLD HERE FIRST/ LIPAT DI SINI DAHULU

To:

Pharmacovigilance Section  
1<sup>st</sup> Floor, Department of Pharmaceutical Services Building  
Simpang 433, Rimba Highway  
Kg Madaras, Bandar Seri Begawan  
BB1514  
Brunei Darussalam  
Telephone Number: +673 2392398/ 2393301 Ext 201, 206, 207  
Fax Number: +673 2393097  
E-mail: productdefect.pharmacy@moh.gov.bn

FOLD HERE SECOND/ LIPAT DI SINI KEMUDIAN