

ASEAN POST-MARKETING ALERT SYSTEM (Form B)
(Use this form for multiple product alerts of same product type with similar issues)

<p><i>Tick ✓</i></p> <p>1. Level of confidentiality: <input type="checkbox"/> Internal / Restricted circulation <input checked="" type="checkbox"/> On public domain, specify website: www.npra.moh.gov.my _____</p>	<p>2. Issue: <input checked="" type="checkbox"/> Adulteration <input type="checkbox"/> Counterfeit <input type="checkbox"/> Quality defect <input type="checkbox"/> Safety aspect <input type="checkbox"/> Others, please specify: _____</p>	<p>3. Action: <input type="checkbox"/> Cancellation of registration <input type="checkbox"/> Labelling revision <input checked="" type="checkbox"/> Recall of product <input type="checkbox"/> Suspension of registration <input type="checkbox"/> Withdrawal of product <input checked="" type="checkbox"/> Others, please specify: Cancellation of notification. _____</p>
<p>4. Source / Type of signal:</p>	<input type="checkbox"/> Local ADR reports <input type="checkbox"/> Scientific literature / local studies <input checked="" type="checkbox"/> Post-market sampling and testing activities _____	<input type="checkbox"/> Decision made by other regulatory authorities &/or industry <input type="checkbox"/> Others, please specify: _____
Product information (whenever possible, please provide an image of the product)		
<p>5. Product type:</p>	<input type="checkbox"/> Biologic <input checked="" type="checkbox"/> Cosmetic <input type="checkbox"/> Health supplement <input type="checkbox"/> Pharmaceutical _____	<input type="checkbox"/> Traditional medicine <input type="checkbox"/> Others, please specify: _____
<p>6. Forensic classification in your country:</p>	<input checked="" type="checkbox"/> General sales list / Over-the-counter <input type="checkbox"/> Pharmacy only _____	<input type="checkbox"/> Prescription only <input type="checkbox"/> Others, please specify: _____
Reporting country / authority		
<p>7. Name of country / Issuing authority: Malaysia, National Pharmaceutical Regulatory Agency</p>	<p>8. Report reference no.: 1-4/2018/K</p>	
<p>9. Department / Designation of person issuing the alert: National Pharmaceutical Regulatory Agency, Ministry Of Health Malaysia</p>	<p>10. Date of report: 2 January 2018</p>	
Contact person		
<p>11. Name: MS WAN MOHAINA BINTI WAN MOHAMMAD</p>	<p>12. Department / Designation: Deputy Director Centre of Post Registration of Product and Cosmetic Control, National Pharmaceutical Regulatory Agency, Ministry Of Health Malaysia</p>	
<p>13. Email address: wanmohaina@npra.gov.my</p>	<p>14. Contact no. Telephone no.: +6-03-78835538 Fax no.: + 6-03-79567151</p>	

Annex I

Report reference no.:

ASEAN ALERT 1-4/2018/K

Date of report:

2 January 2018

No	Description of product *				Marketing authorisation holder / Product licence holder /Company responsible for placing product in the market	Manufacturer	Investigations i.e.	Actions i.e.
	Brand / Product name / Alternative name (e.g. local language)	<ul style="list-style-type: none"> Active ingredients / Generic name / Full formula (for cosmetics, traditional medicines etc.) Strength (if applicable): 	<ul style="list-style-type: none"> Dosage form / Pack size (if applicable) Batch / Lot number Date of Expiry or Manufacture (if applicable) 	Intended use as listed on label:				
1.	Nuriz Shoppe -UV Pearl Cream	NA	NA	NA	Progressive Mix Industries	Progressive Mix Industries, Malaysia	Products tested and found to contain high level of mercury.	<ul style="list-style-type: none"> Notification of these products has been cancelled. Company has to destroy the recalled products.
2.	Nuriz- D'solve	NA	NA	NA				
3.	Aura Gorgeous Night Cream	NA	BN: AG201	NA	Aura Gorgeous Beauty & Healthy	Anfa International Laboratoires, Morocco		
4.	NV Anti Blemish Toner 1	NA	NA	NA	Nouvelle Beauty Centre Sdn Bhd	QEMRICH SDN. BHD., Malaysia	Products tested and found to contain hydroquinone and tretinoin.	

Nuriz Shoppe -UV Pearl Cream



Nuriz- D'solve



Aura Gorgeous Night Cream



NV Anti Blemish Toner 1

