05 July 2017

Urgent Field Safety Notice
NovoPen Echo® and NovoPen® 5
Ref. 2016050310

Important NovoPen Echo® and NovoPen® 5 information

Dear Healthcare Professional,

We wish to advise you that a number of batches of NovoPen® 5 and NovoPen Echo® are being recalled to **pharmacy level** with immediate effect. Novo Nordisk has identified that the insulin cartridge holder from affected batches may crack or break if exposed to certain chemicals such as certain cleaning agents. NovoPen Echo® and NovoPen® 5 are durable insulin delivery devices designed for use with Novo Nordisk Penfill® cartridges.

A picture of the cartridge holder is shown in Figure 1.

Figure 1. Picture of cartridge holder used for NovoPen Echo® and NovoPen® 5.

Details of affected devices:

The affected NovoPen Echo® and NovoPen® 5 LOT/batch numbers distributed in Ireland are shown in Table 1. Please note the LOT/batch number can differ very slightly on the pen and the box that it comes in.

NovoPen Echo®		**NovoPen® 5**	
LOT/batch number on carton	**LOT/batch number on device**	**LOT/batch number on carton**	**LOT/batch number on device**
DUG0191	DUG0191	EVG0902-2	EVG0902
DUG0192	DUG0192	EVG2293-1	EVG2293
DUG0193	DUG0193	EVG2910-2	EVG2910
DUG1613	DUG1613	EVG3008-1	EVG3008
DUG1614	DUG1614	EVG6245-1	EVG6245
DUG1615	DUG1615	FVG7150-1	FVG7150
DUG1616	DUG1616	FVG7565-2	FVG7565
DUG1708	DUG1708	FVG7566-2	FVG7566
DUG1709	DUG1709	FVG7612-1	FVG7612
DUG1775	DUG1775	FVG7613-1	FVG7613

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DUG1776	DUG1776	FVG7613-2	FVG7613
DUG1778	DUG1778	FVG7616-1	FVG7616
DUG2049	DUG2049	FVG7617-2	FVG7617
DUG2053	DUG2053	FVG8531-2	FVG8531
DUG2129-1	DUG2129	FVG8532-1	FVG8532
EVG2298-6	EVG2298	FVG8654-2	FVG8654
EVG2300-2	EVG2300	FVG8657-2	FVG8657
EVG2909-1	EVG2909		
EVG3999-2	EVG3999		
EVG5963-3	EVG5963		
EVG6823-2	EVG6823		
FVG7337-5	FVG7337		
FVG7364-1	FVG7364		
FVG7457-1	FVG7457		
FVG8212-3	FVG8212		
FVG8217-1	FVG8217		
FVG8218-1	FVG8218		
FVG8995-1	FVG8995		
FVG8997-4	FVG8997		

Table 1. List of affected NovoPen Echo® and NovoPen® 5 LOT/batch numbers in Ireland

Description of the problem:

If the cartridge holder comes into contact with certain chemicals e.g. certain cleaning agents, against guidance in the Instructions For Use, the plastic materials used can be weakened resulting in cracking or breaking. When cleaning the pen as described in Instructions For Use, there is no reason to believe that cracking of the cartridge holder will occur.

Novo Nordisk has already changed the material of the cartridge holder back to the original type, where the issue with cracked and broken cartridge holders was not seen.

Using a device with a cracked/broken cartridge holder can result in the device delivering a smaller than intended insulin dose leading to an increase in blood sugar levels. The risk of experiencing high blood sugar levels with the use of a device with an affected cartridge holder is evaluated to be less than 0.1% i.e. less than 1 in 1000 patients will experience high blood sugar levels due to an affected cartridge holder.

The warning symptoms of high blood sugar (hyperglycaemia) normally appear gradually and can be: flushed, dry skin; feeling sleepy or tired; dry mouth, fruity (acetone) breath; urinating more often, feeling thirsty; loss of appetite or feeling or being sick (nausea or vomiting).
Patients may not experience any physical signs of high blood sugar levels, but may only see the high readings in their blood sugar measurements.

This issue is being coordinated by pharmacists in Ireland. We are also making patients aware of the issue via appropriate networks including Diabetes Ireland and the Irish media.

If you in your hospital or clinic are in possession of NovoPen Echo® and/or a NovoPen® 5 device with the affected LOT/batch number, please immediately quarantine and contact Novo Nordisk on 1850 665 665 to order replacement stock and arrange for the return of affected stock.

- Batch numbers of unopened NovoPen Echo® and NovoPen® 5 devices are printed on the back of the outer packaging/carton (Figure 2.).

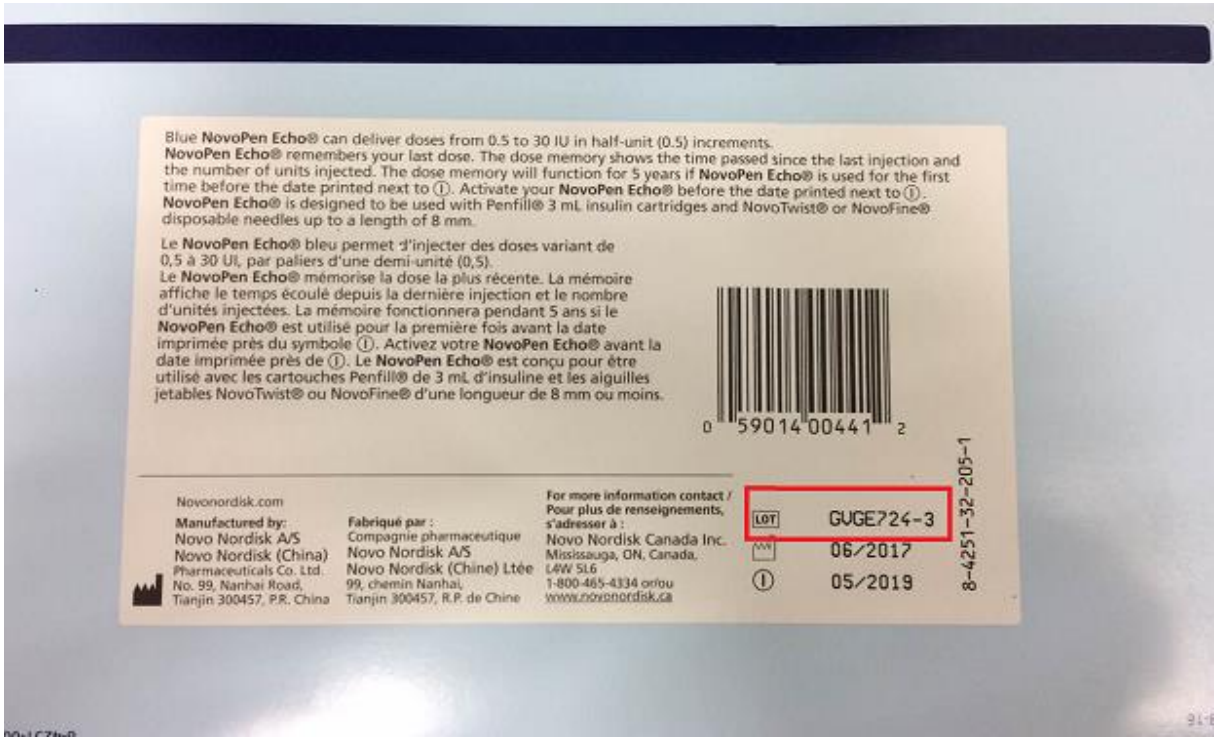

Figure 2. Red square shows where the LOT/batch number is located on a NovoPen Echo® and NovoPen® 5 e.g. the LOT/batch number on the above device is GVGE724-3

- For NovoPen Echo® and NovoPen® 5 devices separated from their outer packaging/carton, the LOT/batch numbers are printed on NovoPen Echo® and NovoPen® 5 as indicated in Figure 3.

A **B**

Figure 3. Red squares show where the LOT/batch number is located on A) NovoPen Echo® and B) NovoPen® 5. e.g. the LOT/batch number on the NovoPen Echo® to the left is FVG7364.

Information for Patients
If you have patients that contact you that are using NovoPen Echo® and/or NovoPen® 5 with one of the above-mentioned batch numbers:

- Attached is an information letter that may be shared with these patients and which provides contact details for Novo Nordisk in order to arrange a replacement cartridge holder.

For patients using a NovoPen Echo® or NovoPen® 5 device with a batch number not mentioned above, there is no reason for concern and they can continue their treatment as usual.

Follow-up action

Novo Nordisk will continue to monitor safety issues reported with the affected LOT/batch numbers and will communicate if any new relevant information becomes available.

Reporting of safety issues

Please report any safety issue to the Health Products Regulatory Authority (HPRA):
Earlsfort Terrace; IRL – Dublin 2
Tel: +353 1 6764971; E-mail: devicesafety@hpra.ie; Website: www.hpra.ie

Safety issues should also be reported to Novo Nordisk on 1850 665 665.

The safety of patients is of utmost importance for Novo Nordisk. We apologise for any inconvenience that this issue may cause. If you require any further information related to this recall, please contact Novo Nordisk on 1850 665 665.

Yours sincerely,

Dr Donna Sexton
Clinical, Medical and Regulatory Manager - Ireland

Date of preparation: July 2017
IR/DV/0717/0050

Urgent Field Safety Notice
Important Safety Information
NovoPen Echo® and NovoPen® 5
Ref. 2016050310

05 July 2017

Dear Patient,

Novo Nordisk A/S has detected that the insulin cartridge holder used in a number of NovoPen Echo® and NovoPen® 5 batches may crack or break if exposed to certain chemicals in some household products, such as cleaning agents. NovoPen Echo® and NovoPen® 5 are used for insulin treatment by people with diabetes.

Novo Nordisk urges people with diabetes using a NovoPen Echo® and/or NovoPen® 5 from one of the affected batches to contact Novo Nordisk in order to replace the cartridge holder, which is just one component of the device, as some could be damaged. Please check your device LOT/batch number against the list of affected LOT/batch numbers below.

A picture of the cartridge holder is shown in Figure 1.

Figure 1. Cartridge holder used for NovoPen Echo® and NovoPen® 5.

Description of the problem:
If the cartridge holder comes in contact with certain chemicals it can crack or break. The reason for the cracking is that the plastic materials used for the cartridge holders in the affected batches can be weakened if exposed to certain chemicals found in some household products such as cleaning agents.

When cleaning the device as described in the Instructions For Use, cracking of the cartridge holder is extremely unlikely.

Novo Nordisk has already changed the material of the cartridge holder back to the original type, where the issue with cracked and broken cartridge holders was not seen.

Using a device with a cracked/broken cartridge holder could result in the device delivering a smaller dose of insulin than expected leading to high blood sugar levels. The risk of experiencing high blood sugar levels with the use of a device with an affected cartridge holder is evaluated to be less than 0.1%, i.e. less than 1 in 1000 patients will experience high blood sugar levels due to an affected cartridge holder.

The warning symptoms of high blood sugar levels (hyperglycaemia) normally appear gradually and can be: flushed, dry skin; feeling sleepy or tired; dry mouth, fruity

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Registration No.:
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(acetone) breath; urinating more often, feeling thirsty; and losing your appetite, feeling or being sick (nausea or vomiting).

You might not experience any physical signs of high blood sugar levels, but only be able to see it in your blood sugar measurements.

Details of affected devices:
The affected NovoPen Echo® and NovoPen® 5 LOT/batch numbers distributed in Ireland are shown in the below table. Please note the batch number can differ very slightly on the pen and the box that it comes in.

NovoPen Echo®		**NovoPen® 5**	
LOT/batch number on carton	**LOT/batch number on device**	**LOT/batch number on carton**	**LOT/batch number on device**
DUG0191	DUG0191	EVG0902-2	EVG0902
DUG0192	DUG0192	EVG2293-1	EVG2293
DUG0193	DUG0193	EVG2910-2	EVG2910
DUG1613	DUG1613	EVG3008-1	EVG3008
DUG1614	DUG1614	EVG6245-1	EVG6245
DUG1615	DUG1615	FVG7150-1	FVG7150
DUG1616	DUG1616	FVG7565-2	FVG7565
DUG1708	DUG1708	FVG7566-2	FVG7566
DUG1709	DUG1709	FVG7612-1	FVG7612
DUG1775	DUG1775	FVG7613-1	FVG7613
DUG1776	DUG1776	FVG7613-2	FVG7613
DUG1778	DUG1778	FVG7616-1	FVG7616
DUG2049	DUG2049	FVG7617-2	FVG7617
DUG2053	DUG2053	FVG8531-2	FVG8531
DUG2129-1	DUG2129	FVG8532-1	FVG8532
EVG2298-6	EVG2298	FVG8654-2	FVG8654
EVG2300-2	EVG2300	FVG8657-2	FVG8657
EVG2909-1	EVG2909		
EVG3999-2	EVG3999		
EVG5963-3	EVG5963		
EVG6823-2	EVG6823		
FVG7337-5	FVG7337		
FVG7364-1	FVG7364		
FVG7457-1	FVG7457		
FVG8212-3	FVG8212		
FVG8217-1	FVG8217		
FVG8218-1	FVG8218		

FVG8995-1	FVG8995		
FVG8997-4	FVG8997		

Table 1. List of affected NovoPen Echo® and NovoPen® 5 LOT/batch numbers in Ireland

Batch numbers of unopened NovoPen Echo® and NovoPen® 5 devices are printed on the back of the outer packaging/carton (Figure 2).

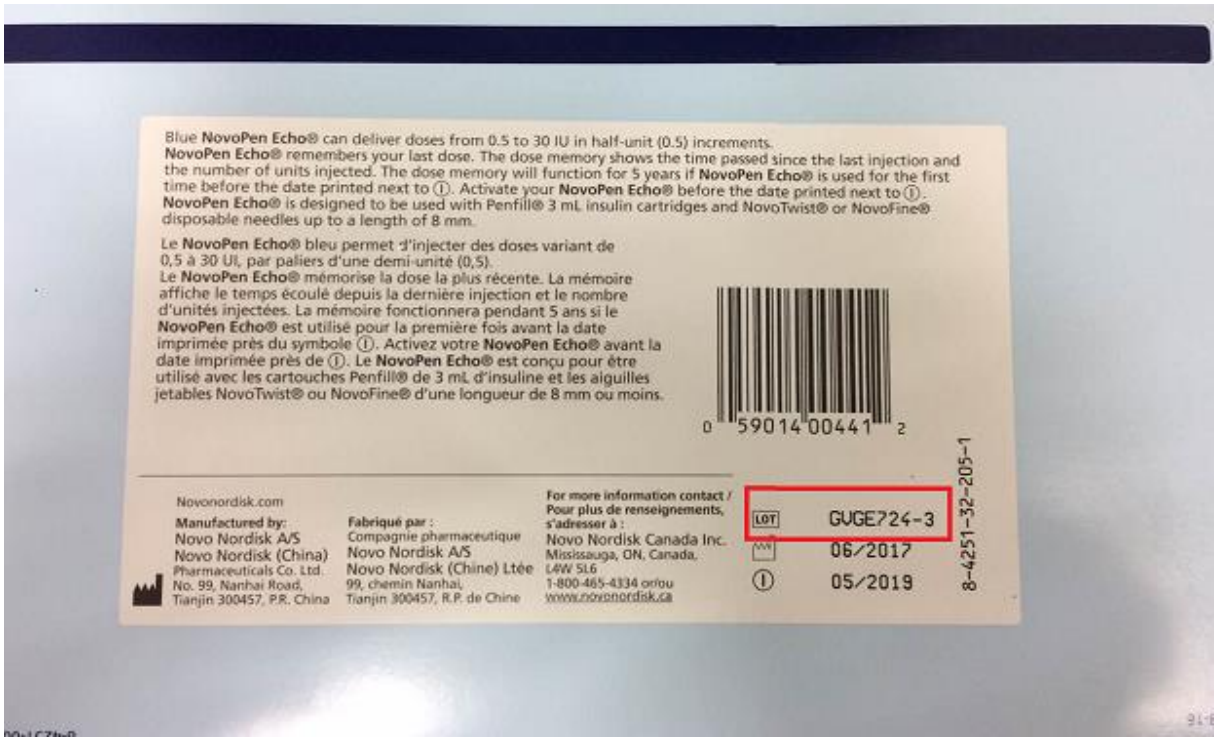

Figure 2. Red square shows where the LOT/batch number is located on a NovoPen Echo® and NovoPen® 5 e.g. the LOT/batch number on the above device is GVGE724-3

For NovoPen Echo® and NovoPen® 5 devices separated from their outer packaging/carton, the LOT/batch numbers are printed on NovoPen Echo® and NovoPen® 5 as indicated in Figure 3.

A **B**

Figure 3. Red squares show where the LOT/batch number is located on A) NovoPen Echo® and B) NovoPen® 5. e.g. the LOT/batch number on the NovoPen Echo® to the left is FVG7364.

If you are in possession of a NovoPen Echo® and/or a NovoPen® 5 with a LOT/batch number which is **not** mentioned above, there is no reason for concern and you can be confident that the device will work as intended.

What to do if you are using a NovoPen Echo® and/or NovoPen® 5 with one of the above-mentioned batch numbers:

- Do **not** stop treatment without consulting your healthcare professional.
- Be attentive to your blood sugar levels by checking them regularly and looking for symptoms of hyperglycaemia. If you note these symptoms, measure your blood sugar levels as instructed by your healthcare professional and take appropriate action.
- In the event that you experience symptoms of high blood sugar levels involving this product, contact your healthcare professional for advice.
- To request a replacement cartridge holder, register your contact details (name, address, phone number, email and number of affected cartridge holders) at www.novonordisk.com or contact Novo Nordisk on 1850 665 665.
- Upon receipt, you should attach the new cartridge holder and use as stated in the Instructions For Use.
- Report any safety issues to Novo Nordisk on 1850 665 665 or complaintireland@novonordisk.com

The safety of patients is of utmost importance for Novo Nordisk. We strive to produce and distribute the highest quality products for your use. We sincerely apologise for this unfortunate situation and the concerns and inconvenience it may cause.

If you require any further information related to this recall, please contact Novo Nordisk on 1850 665 665.

Yours sincerely,

Dr Donna Sexton
Clinical, Medical and Regulatory Manager - Ireland

Date of preparation: July 2017
IR/DV/0717/0051

05 July 2017

Urgent Field Safety Notice
NovoPen Echo® and NovoPen® 5
Ref. 2016050310

Important NovoPen Echo® and NovoPen® 5 information

Dear Pharmacist,

We wish to advise you that a number of batches of NovoPen® 5 and NovoPen Echo® are being recalled to **pharmacy level** with immediate effect. Novo Nordisk has identified that the insulin cartridge holder from affected batches may crack or break if exposed to certain chemicals such as certain cleaning agents. NovoPen Echo® and NovoPen® 5 are durable insulin delivery devices designed for use with Novo Nordisk Penfill® cartridges.

Novo Nordisk urges people with diabetes using a NovoPen Echo® and/or NovoPen® 5 from one of the affected batches to replace the cartridge holder as some could be damaged.

A picture of the cartridge holder is shown below (Figure 1)

Figure 1. Picture of cartridge holder used for NovoPen® Echo® and NovoPen® 5.

Details of affected devices

The affected NovoPen Echo® and NovoPen® 5 LOT/batch numbers distributed in Ireland are shown in Table 1. Please note the LOT/batch number can differ very slightly on the pen and the box that it comes in.

NovoPen Echo®		**NovoPen® 5**	
LOT/batch number on carton	**LOT/batch number on device**	**LOT/batch number on carton**	**LOT/batch number on device**
DUG0191	DUG0191	EVG0902-2	EVG0902
DUG0192	DUG0192	EVG2293-1	EVG2293
DUG0193	DUG0193	EVG2910-2	EVG2910
DUG1613	DUG1613	EVG3008-1	EVG3008
DUG1614	DUG1614	EVG6245-1	EVG6245

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DUG1615	DUG1615	FVG7150-1	FVG7150
DUG1616	DUG1616	FVG7565-2	FVG7565
DUG1708	DUG1708	FVG7566-2	FVG7566
DUG1709	DUG1709	FVG7612-1	FVG7612
DUG1775	DUG1775	FVG7613-1	FVG7613
DUG1776	DUG1776	FVG7613-2	FVG7613
DUG1778	DUG1778	FVG7616-1	FVG7616
DUG2049	DUG2049	FVG7617-2	FVG7617
DUG2053	DUG2053	FVG8531-2	FVG8531
DUG2129-1	DUG2129	FVG8532-1	FVG8532
EVG2298-6	EVG2298	FVG8654-2	FVG8654
EVG2300-2	EVG2300	FVG8657-2	FVG8657
EVG2909-1	EVG2909		
EVG3999-2	EVG3999		
EVG5963-3	EVG5963		
EVG6823-2	EVG6823		
FVG7337-5	FVG7337		
FVG7364-1	FVG7364		
FVG7457-1	FVG7457		
FVG8212-3	FVG8212		
FVG8217-1	FVG8217		
FVG8218-1	FVG8218		
FVG8995-1	FVG8995		
FVG8997-4	FVG8997		

Table 1. List of affected NovoPen Echo® and NovoPen® 5 LOT/batch numbers in Ireland

Description of the problem

If the cartridge holder comes into contact with certain chemicals e.g. certain cleaning agents, against guidance in the Instructions For Use, the plastic materials used can be weakened resulting in cracking or breaking. When cleaning the pen as described in Instructions For Use, there is no reason to believe that cracking of the cartridge holder will occur.

Novo Nordisk has already changed the material of the cartridge holder back to the original type where the issue with cracked and broken cartridge holders was not seen.

Using a device with a cracked/broken cartridge holder can result in the device delivering a smaller than intended insulin dose leading to an increase in blood sugar levels. The risk of experiencing high blood sugar levels with the use of a device with an affected cartridge holder is evaluated to be less than 0.1% i.e. less than 1 in 1000 patients will experience high blood sugar levels due to an affected cartridge holder.

The warning symptoms of high blood sugar (hyperglycaemia) normally appear gradually and can be: flushed, dry skin; feeling sleepy or tired; dry mouth, fruity (acetone) breath; urinating more often, feeling thirsty; loss of appetite or feeling or being sick (nausea or vomiting).
Patients may not experience any physical signs of high blood sugar levels, but may only see the high readings in their blood sugar measurements.

Required actions
Pharmacy Level Recall

- Please inspect all NovoPen Echo® and NovoPen® 5 devices you have in your possession for the affected LOT/batch numbers. For hospital pharmacies, this includes wards, clinics and any other relevant locations within your facility.

- Batch numbers of unopened NovoPen Echo® and NovoPen® 5 devices are printed on the back of the outer packaging/carton (Figure 2).

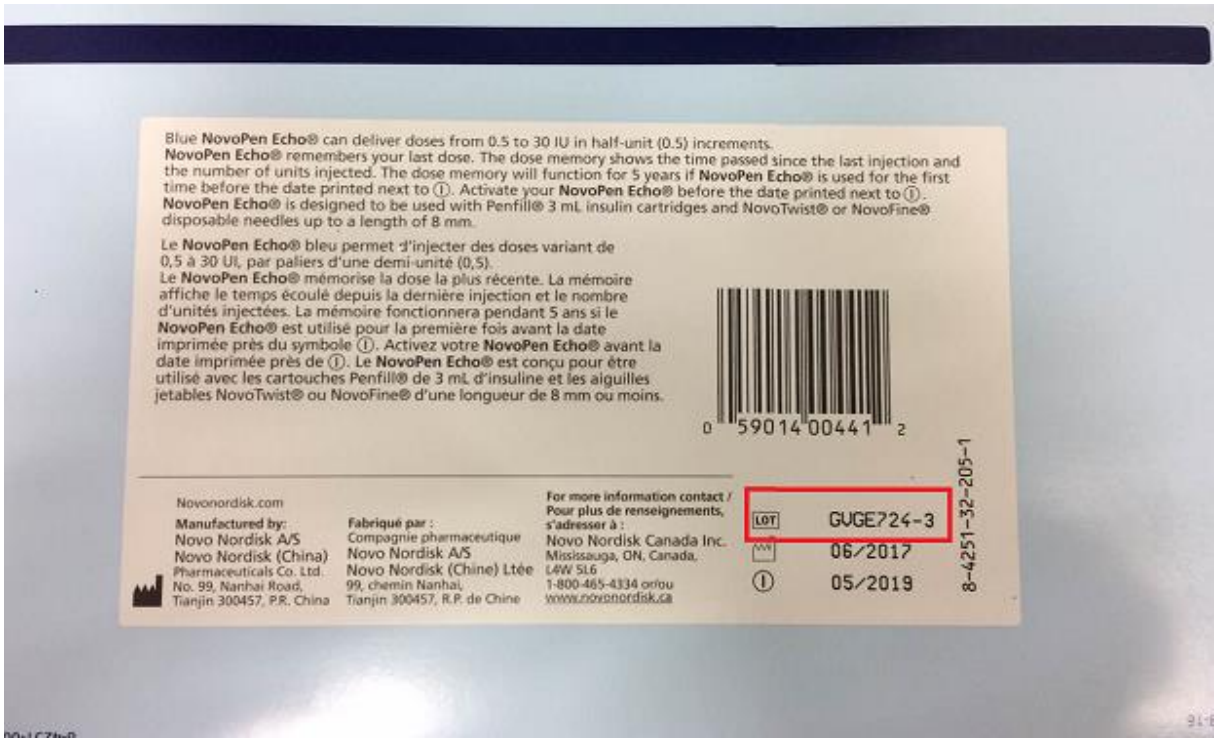

Figure 2. Red square shows where the LOT/batch number is located on a NovoPen Echo® and NovoPen® 5 e.g. the LOT/batch number on the above device is GVGE724-3

- For NovoPen Echo® and NovoPen® 5 devices separated from their outer packaging/carton, the LOT/batch numbers are printed on NovoPen Echo® and NovoPen® 5 as indicated in Figure 3.

A **B**

Figure 3. Red squares show where the LOT/batch number is located on A) NovoPen Echo® and B) NovoPen® 5. e.g. the LOT/batch number on the NovoPen Echo® to the left is FVG7364.

Please immediately quarantine any devices you have in your possession from any of the affected LOT/batch numbers and contact Novo Nordisk on 1850 665 665 to order replacement stock and arrange for the return of affected stock.

Advice for patients who present with a NovoPen Echo® and/or NovoPen® 5 device from one of the above-mentioned batch numbers

- Please ask the patient to register contact details (name, address, phone number, email and number of affected cartridge holders)
  - via the Novo Nordisk corporate website www.novonordisk.com
  - by contacting Novo Nordisk Ireland on 1850 665 665

Reporting of safety issues

Please report any safety issue to the Health Products Regulatory Authority (HPRA):
Earlsfort Terrace; IRL – Dublin 2
Tel: +353 1 6764971; E-mail: devicesafety@hpra.ie; Website: www.hpra.ie

Safety issues should also be reported to Novo Nordisk on 1850 665 665.

The safety of patients is of utmost importance for Novo Nordisk. We apologise for any inconvenience that this issue may cause. If you require any further information related to this recall, please contact Novo Nordisk on 1850 665 665.

Yours sincerely,

D Sexton

Dr Donna Sexton
Clinical, Medical and Regulatory Manager - Ireland

Date of preparation: July 2017
IR/DV/0717/0049