

Patient Group Direction (PGD) for the Administration of

ADRENALINE (Epinephrine) INJECTION For The TREATMENT of ANAPHYLAXIS

by Registered Professionals to Individuals Accessing NHS Services in
Durham, Darlington, Tees, North Cumbria, Northumberland and Tyne & Wear

**YOU MUST BE AUTHORISED BY NAME,
UNDER THE CURRENT VERSION OF
THIS PGD BEFORE YOU ATTEMPT TO
WORK ACCORDING TO IT.**


Direction Number: - NECSAT 2018/007

Valid from: 1st September 2018

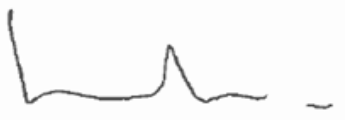
Review date: May 2020

Expiry date: 31st August 2020

This patient group direction has been developed & produced by: -

Title	Name	Signature	Date
Medicines Optimisation Pharmacist (Lead Author) <small>(North of England Commissioning Support)</small>	Hira Singh <i>(Pharmacist)</i> <i>(Lead Author)</i>		31/07/18
Medicines Optimisation Pharmacist <small>(North of England Commissioning Support)</small>	Sue White <i>(Pharmacist)</i>		05/08/18
<i>Assistant Medical Director</i> <small>(NHS England, Cumbria and North East)</small>	Dr James Gossow <i>(Doctor)</i>		24/08/18
Immunisation and Screening Manager <small>(NHS England, Cumbria and North East)</small>	Aline Marron <i>(Nurse)</i>		14/08/18

This PGD has been approved for use in Cumbria, Northumberland, Tyne & Wear by: -

Title	Name	Signature	Date
<i>Deputy Medical Director</i> <small>(NHS England, Cumbria and North East)</small>	Dr Johnathan Slade <i>(Governance Authorisation)</i>		25/08/18

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

Patients in whom an anaphylactic reaction is identified

Objectives of care

To treat anaphylaxis and to preserve life

Inclusion criteria

[NB. Only use those criteria that are specific to your authorised role & competence. Ensure appropriate consent/best interest decision has been obtained before commencing].

Emergency treatment of acute anaphylaxis

All who treat anaphylaxis should be aware of the potential for confusion between anaphylaxis and syncope and panic attacks.

Anaphylaxis is likely when the following 3 criteria are met: -

- 1) Sudden onset and rapid progression of symptoms
- 2) Life-threatening Airway and/or Breathing and/or Circulation problems
- 3) Skin and/or mucosal changes (flushing, urticaria, angioedema)

Please note: A single set of criteria will not identify all anaphylactic reactions. There is a range of signs and symptoms, none of which are entirely specific. Refer to [Appendix 1](#) for a summary of information on recognition of anaphylactic reactions and the online "Emergency treatment of anaphylactic reactions - Guidelines for healthcare providers (Resuscitation Council (UK) 2008)" for full details (<https://www.resus.org.uk/anaphylaxis/emergency-treatment-of-anaphylactic-reactions/>).

Please refer to [Resus guidance 2015 Resuscitation Council \(UK\) October 2015](#) for additional information on basic life support (<https://www.resus.org.uk/statements/rc-uk-resuscitation-guidelines-2015-published/>)

Exclusion criteria (Refer to current SPC and Green Book Guidance (Online version) for additional details)

- Previous allergy to adrenaline.
- Other contra-indications are relative as adrenaline is being administered in an emergency situation.

Action if excluded

- Call 999 Emergency services and/or refer to doctor as appropriate. Ensure all actions/decisions are documented.

Action if patient declines treatment

Not considered likely but: -

- Ensure patient, parent or guardian fully understands risks of declining treatment.
- Call 999 Emergency services and/or refer to doctor as appropriate.
- Document refusal and advice given in medical notes (written or electronic).

2. Description of Treatment.

Name, strength & formulation of drug:

Adrenaline (epinephrine)	1mg/1ml	(1 in 1000) solution for injection	ampoules
Adrenaline (epinephrine)	500mcg/0.5ml	(1 in 1000) solution for injection	ampoules
Adrenaline (epinephrine)	500mcg (single dose)	(1 in 1000) solution for inj. (pre-filled syringe)	auto-injector
Adrenaline (epinephrine)	300mcg (single dose)	(1 in 1000) solution for inj. (pre-filled syringe)	auto-injector
Adrenaline (epinephrine)	150mcg (single dose)	(1 in 1000) solution for inj. (pre-filled syringe)	auto-injector
Adrenaline (epinephrine)	150mcg (single dose)	(1 in 2000) solution for inj. (pre-filled syringe)	auto-injector

Legal Status:

POM – Prescription Only Medicine

(NB. POM restriction does not apply to adrenaline injection 1mg/ml where administration is for saving life in emergency)

Dosage/Dose range:

The dose regime of **intramuscular** adrenaline 1 in 1000 (1mg/ml)

Age	Dose	Volume (1mg/ml)
Adult and child more than 12 years	500 micrograms (or 0.5mg) (300 micrograms (or 0.3mg) if child is small or pre-pubertal)	0.5ml ¹
Child 6 –12 years:	300 micrograms (or 0.3mg) = 0.3ml	0.3ml
Child less than 6 years old	150 micrograms (or 0.15mg) = 0.15ml	0.15ml ²

- **Repeat the IM adrenaline dose if there is no improvement in the patient's condition.**
- **Further doses can be given at about 5-minute intervals according to the patient's response.**

- ¹ 300mcg (0.3ml) if child is small or pre-pubertal. ² Use suitable syringe for measuring small volume.
- Auto-injectors for self-administration of adrenaline should not be used as a substitute for a proper anaphylaxis pack. However, if an adrenaline auto-injector is the only available adrenaline preparation when treating anaphylaxis, health care providers should use it.

Route/Method:

Intra-muscular (IM) injection (preferably mid-point in anterolateral thigh)

Frequency of Administration:

If no improvement occurs in patient's condition, or condition deteriorates after initial response, **dose may be repeated if necessary at 5-minute intervals**, according to blood pressure, pulse and respiratory function.

Maximum dose / Maximum number of vaccinations:

Maximum dose: 500mcg

Maximum number of treatments: No limit – (determined by patient response)**

** (For additional information, refer to the Resuscitation Guidance (UK) (2015), *Emergency treatment of anaphylactic reactions – Guidelines for healthcare providers*).

Follow up treatment:

- **Dial 999** for immediate referral to Accident & Emergency for assessment and observation

3. Further Aspects of Treatment:

Relevant Warnings & Potential Adverse Effects & Reporting

*Potential Adverse Effects: -

- Anxiety, nausea, tremor, sweating, tachycardia, vomiting, headache, dizziness, cold extremities and dyspnoea

Reporting Procedure of Adverse Effects

- Report to doctor as appropriate & document in patient's medical records.
- All adverse reactions due to ▼ drugs should be reported to the MHRA using the yellow card system.
- For established vaccines only report serious adverse reaction.
- Please refer to www.mhra.gov.uk/yellowcard and Green Book- Chapter 9 (20th March 2013).

*See manufacturers Summary of Product Characteristics &/or BNF for details of all potential adverse effects and reactions.

Identification and Management of Adverse Reactions

- See anaphylaxis guidelines. Patient/Parent/Guardian requested to report side effects.
- Refer to doctor or other service as appropriate.
- Please be aware of Resuscitation Council Guideline changes (2015).

Please refer to current SPC "special warnings & special precautions for use" section for full details & relevant online chapters of the Green Book.

Advice to Patient / Carer (verbal or written)

To report this reaction before any future medical or dental treatment. / Carry Medic-Alert (or similar)
Patient should be seen by a specialist.

Arrangements for Referral to Medical Advice

- Doctor or ambulance to attend as soon as possible, - (whichever is the most appropriate).
- Patient should attend hospital

Records

The following must be recorded in the patient's notes: -

- Patient's name and date of birth; - Confirmation that there are no contraindications;
- Reason adrenaline is required; - Dose/amount of adrenaline administered;
- Site & route of injection; - Time & date of administration;
- Brand name (if applicable), batch number and expiry date of injection
- Whom administered by and signature of person administering injection (if not recorded on computer).
- Where possible, the time of onset of the anaphylactic reaction (i.e. when symptoms were first noticed).
- Cause of reaction; - Support literature given (as applicable).
- Advice given to patient;
- Outcome (e.g. referral to hospital).
- Any further details as required by the commissioning/authorising organisation

Additional Facilities

- Have access to a resuscitation kit.
- Do not store above 25°C.
- Have access to a telephone.
- Stock control & storage of vaccines in accordance with national and local policies / protocols/ guidelines.
- Access to a current BNF.
- All staff are familiar with and have online access to the latest edition of the Green Book, noting the clinical guidance may change and that the Green Book is frequently updated.
- Any additional requirements as details by the commissioning/authorising organisation.

Special Considerations / Additional Information

- **Patients having an anaphylactic reaction should be recognised and treatment should be based on general life support principles** (*please be aware of latest resuscitation (2015) guidelines*) : -
 - Use the Airway, Breathing, Circulation, Disability and Exposure (ABCDE) approach to recognise and treat problems.
 - Call for help early.
 - Treat the greatest threat to life first.
 - Initial treatments should not be delayed by the lack of a complete history or definite diagnosis.
- **Patients having an anaphylactic reaction in any setting should expect the following as a minimum:** -
 - Recognition that they are seriously unwell.
 - An early call for help.
 - Initial assessment and treatments based on an ABCDE approach, (see Appendix 2).
 - Adrenaline therapy if indicated.
 - Investigation and follow-up by an allergy specialist.

References

- **NICE:** Good Practice Guidance (August 2013) – Patient Group Directions.
- **NHS Executive HSC 2000/026** (9th August 2000): Patient Group Directions [England only].
- **Resuscitation Council (UK)**, Emergency Treatment of anaphylactic reactions Guidelines for healthcare providers. Working Group of the Resuscitation Council (UK). January 2008. Web version accessed on 25/07/2018 and available from <http://www.resus.org.uk/pages/reaction.pdf>
- **Resuscitation Council (UK)**, Resuscitation Guidelines 15th October 2015; (accredited by NICE July 2012). Web version accessed on 31/07/2018 and available from <https://www.resus.org.uk/statements/rc-uk-resuscitation-guidelines-2015-published/>
- **Public Health England** (web version only). August 2012: Vaccine safety and the management of adverse events following immunisation. Immunisation Against Infectious Disease. The “Green Book”. . Accessed on 31/07/18 at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/147868/Green-Book-Chapter-8-v4_0.pdf
- **British National Formulary (BNF)**, current edition. Available at <https://www.bnf.org/products/bnf-online/>
- **Nursing and Midwifery Council (NMC), 2007:** Standards for Medicines Management.
- **Nursing and Midwifery Council (NMC), 2007:** Record Keeping Advice Sheet.
- **Nursing and Midwifery Council (NMC), 2008:** Code of Professional Conduct: standards of conduct, performance & ethics for nurses and midwives.
- **Martindale Pharma**, Adrenaline (Epinephrine) 1:1000 Injection for Anaphylaxis (glass prefilled syringe). Summary of Product Characteristics (SPC), 20/12/17. Accessed from eMC on 31/07/18. Available at <http://www.emc.medicines.org.uk>
- **Martindale Pharma**, Adrenaline (Epinephrine) 1:1000 (1mg/ml) solution for injection (glass ampoules). SPC, 16/04/18. Accessed from eMC on 31/07/18. Available at <http://www.emc.medicines.org.uk>
- **Hameln Pharmaceutical Ltd**, Adrenaline (Epinephrine) Injection BP 1 in 1000. SPC, 18/12/15. Accessed from eMC on 31/07/18. Available at <http://www.emc.medicines.org.uk>
- **Concordia International (formerly AMCo)**, Adrenaline (Epinephrine) 1:1000 Solution for Injection. SPC 29/12/15. Accessed from eMC on 31/07/18. Available at <http://www.emc.medicines.org.uk>
- **Bausch & Lomb U.K Limited**, Emerade, 500mcg, solution for injection in pre-filled pen. – SPC, 20/01/17. Accessed from Electronic Medicines Compendium (eMC) on 31/07/18. Available at <http://www.emc.medicines.org.uk>
- **Bausch & Lomb U.K Limited**, Emerade, 300mcg, solution for injection in pre-filled pen. - SPC, 20/01/17. Accessed from Electronic Medicines Compendium on 31/07/18. Available at <http://www.emc.medicines.org.uk>
- **Bausch & Lomb U.K Limited**, Emerade, 150mcg, solution for injection in pre-filled pen. SPC, 20/01/17. Accessed from Electronic Medicines Compendium (eMC) on 31/07/18. Available at <http://www.emc.medicines.org.uk>
- **Mylan Products Limited**, EpiPen® Adrenaline (Epinephrine) Auto Injector 0.3 mg. SPC, 29/05/18. Accessed from Electronic Medicines Compendium (eMC) on 31/07/18. Available at <http://www.emc.medicines.org.uk>
- **Meda Pharmaceuticals**, EpiPen® Jr Adrenaline (Epinephrine) Auto Injector 150mcg/0.3ml (1 in 2000). - SPC, 29/05/18. Accessed from Electronic Medicines Compendium (eMC) on 31/07/18. Available at <http://www.emc.medicines.org.uk>
- **ALK-Abello Ltd**, Jext 300 micrograms Solution for Injection in pre-filled pen - Summary of Product Characteristics (SPC), 02/07/18. Accessed from Electronic Medicines Compendium on 31/07/18. Available at <http://www.emc.medicines.org.uk>
- **ALK-Abello Ltd**, Jext 150 micrograms solution for injection in pre-filled pen - Summary of Product Characteristics (SPC), 02/07/18. Accessed from Electronic Medicines Compendium on 31/07/18. Available at <http://www.emc.medicines.org.uk>

4. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically authorised by their clinical lead/supervisor/manager may use this PGD for the indications defined within it.

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

Pharmacists	Nurses	Chiropodists/Podiatrists
Health Visitors	Physiotherapists	Midwives
Dieticians	Optometrists	Registered Orthoptists
Prosthetists and Orthotists	Radiographers	Occupational Therapists
Speech and Language Therapists	Dental Hygienists	Dental Therapists

State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval.

Qualifications required (professional registration applies to specific professions)

Professionals using this PGD must be currently registered with their relevant professional body, e.g.

- For Nurses: - Nursing & Midwifery Council (NMC)
- For Pharmacists: - General Pharmaceutical Council (GPhC)
- For Allied Health Professionals: - Health Professions Council

Additional requirements (applies to all staff)

- Maintain knowledge of vaccinations; either through a recognised course or through in-house training supported by attendance at vaccination study day(s).
- Meet the National minimum standards & competencies in immunisation training as defined in the PHE & RCN publication, "National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners (February 2018)," either through training or professional competence ensuring that annual training is offered to all staff
- Have up to date resuscitation skills and anaphylaxis training (and competent to recognise & manage anaphylaxis).
- Competent to undertake immunisations and have a current authorised Adrenaline PGD.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Have access to a current BNF and *Immunisation against infectious disease* (Green Book).
- Any additional training requirements as deemed necessary by your organisation or authorising body.

Continued training requirements (applies to all staff)

- Annual attendance at an update on resuscitation skills and the management of anaphylaxis within the community/primary care (**mandatory**), which meets the resuscitation council standards.
- Maintenance of own level of updating and competence with evidence of continued professional development.
- Annual updates in immunisation (**recommended**).
- Any continued training requirements as deemed necessary by your organisation or the authorising body.

Recognition of an Anaphylactic Reaction (summarised)

(Please refer to the Resuscitation Council (UK) January 2008 guidelines on “Emergency Treatment of Anaphylactic Reactions” for the full & complete guidance)

Definition of Anaphylaxis

A severe, life-threatening, generalised or systemic hypersensitivity reaction, characterised by rapidly developing life-threatening airway and/or breathing and/or circulation problems usually associated with skin and mucosal changes.

When recognising and treating any acutely ill patient: -

- ABCDE approach must be followed (see also Refer to Resuscitation Council UK for more information) &
- Life threatening problems treated as they are recognised.

Anaphylaxis is likely when all of the following 3 criteria are met: -

- 1) Sudden onset and rapid progression of symptoms
- 2) Life-threatening Airway and/or Breathing and/or Circulation problems
- 3) Skin and/or mucosal changes (flushing, urticaria, angioedema)

The following supports the diagnosis: -

- Exposure to a known allergen for the patient

Remember: -

- Skin or mucosal changes alone are not a sign of an anaphylactic reaction
- Skin and mucosal changes can be subtle or absent in up to 20% of reactions (some patients can have only a decrease in blood pressure, i.e. Circulation problem)
- There can be gastrointestinal symptoms (e.g. vomiting, abdominal pain, incontinence).



1) Sudden onset and rapid progression of symptoms

- The patient will feel and look unwell.
- Most reactions occur over several minutes. Rarely, reactions may be slower in onset.
- The time of onset of an anaphylactic reaction depends on the type of trigger.
- An intravenous trigger will cause a more rapid onset of reaction than stings which, in turn, tend to cause a more rapid onset than orally ingested triggers.
- The patient is usually anxious and can experience a “sense of impending doom”.



2) Life threatening Airways &/or Breathing &/or Circulation problems

Patients can have either an A or B or C problem or any combination. Use the ABCDE approach to recognise these.

Airway problems:

- Airway swelling, e.g., throat and tongue swelling (pharyngeal/laryngeal oedema).
- The patient has difficulty in breathing and swallowing and feels that the throat is closing up.
- Hoarse voice.
- Stridor – this is a high-pitched inspiratory noise caused by upper airway obstruction.

Breathing problems:

- Shortness of breath increased respiratory rate.
- Wheeze
- Patient becoming tired.
- Confusion caused by hypoxia.
- Cyanosis (appears blue) –this is usually a late sign.
- Respiratory arrest.

Circulation problems:

- Signs of shock –pale, clammy.
- Increased pulse rate (tachycardia).
- Decreased conscious level or loss of consciousness.
- Hypotension – feeling faint (dizziness), collapse.
- Anaphylaxis can cause myocardial ischaemia and electrocardiograph (ECG) changes even in individuals with normal coronary arteries.
- Cardiac arrest

The above Airway, Breathing and Circulation problems can all alter the patient's neurological status (**Disability problems**) because of decreased brain perfusion. There may be confusion, agitation and loss of consciousness.

3) Skin and/or mucosal changes

These should be assessed as part of the **Exposure** when using the ABCDE approach.

- They are often the first feature (present in >80% of anaphylactic reactions).
- Can be subtle and dramatic
- There may be just skin, just mucosal, or both skin and mucosal changes.
- There may be erythema – patchy, or generalised, red rash.
- There may be urticaria (also called hives, nettle rash, weals or welts), which can appear anywhere on body. The weals may be pale, pink or red and may look like nettle stings. They can be different shapes and sizes and are often surrounded by a red flare. They are usually itchy.
- Angioedema is similar to urticaria but involves swelling of deeper tissues, most commonly in the eyelids, lips and sometimes in the mouth and throat

NB. Skin changes without life-threatening airway, breathing or circulation problems do not signify an anaphylactic reaction.

Differential diagnosis

Life-threatening conditions

- Sometimes an anaphylactic reaction can present with symptoms and signs that are very similar to life-threatening asthma – this is commonest in children
- A low blood pressure (or normal in children) with a petechial or purpuric rash can be a sign of septic shock.
- Seek help early if there are any doubts about the diagnosis and treatment.
- Following an ABCDE approach will help with treating the differential diagnosis.

Non-life-threatening conditions (these usually respond to simple measures)

- Faint (vasovagal episode).
- Panic attack.
- Breath-holding episode in child.
- Idiopathic (non-allergic) urticaria or angioedema

There can be confusion between an anaphylactic reaction and a panic attack.

Panic attack symptoms may resemble anaphylaxis in some ways: -

- The sense of impending doom and breathlessness leading to hyperventilation.
- There may sometimes be flushing or blotchy skin associated with anxiety, but there is no hypotension, pallor, wheeze, or urticarial rash or swelling.
- Vasovagal attacks post immunisation procedures, but the absence of rash, breathing difficulties and swelling are useful distinguishing features.
- Slow pulse of a vasovagal attack compared with the rapid pulse of a severe anaphylactic episode.
- Fainting usually responds to lying patient down and raising legs.

Appendix 1 continued.

Underlying Principles to note: -

The approach to all critically ill patients, including those who are having an anaphylactic reaction, is the same. (Please see resuscitation (2015) guidelines).

The underlying principles are: -

1. Use an Airway, Breathing, Circulation, Disability, and Exposure (the ABCDEs) approach to assess and treat the patient.
2. Do a complete initial assessment and re-assess regularly.
3. Treat life-threatening problems before moving to the next part of assessment.
4. Assess the effects of treatment.
5. Recognise when you will need extra help. Call for appropriate help early (e.g., calling for an ambulance or resuscitation team).
6. Use all members of the team or helpers. This will enable interventions, e.g., calling for help, assessment, attaching monitoring equipment, and intravenous access, to be undertaken simultaneously.
7. Communicate effectively- use the Situation, Background, Assessment, Recommendation (SBAR) or Reason, Story, Vital signs, Plan (RSVP) approach
8. The aim of the initial treatments is to keep the patient alive, and achieve some clinical improvement. This will buy time for further treatment, making a diagnosis and expert help.
9. Remember - it can take a few minutes for treatments to work, so wait a short while before reassessing the patient after an intervention
10. The ABCDE approach can be used irrespective of your training and experience in clinical assessment or treatment. The detail of your assessment and what treatments you give will depend on your clinical knowledge and skills. If you recognise a problem or are unsure, call for help.

- Patients with Airway and Breathing problems may prefer to sit up as this will make breathing easier.
- Lying flat with or without leg elevation is helpful for patients with a low blood pressure (Circulation problem). If the patient feels faint, do not sit or stand them up - this can cause cardiac arrest.
- Patients who are breathing normally and unconscious should be placed on their side (recovery position).
- Pregnant patients should lie on their left side to prevent caval compression.
- Check patients constantly and be prepared to commence Basic Life Support (BLS) if necessary.

ADRENALINE (Epinephrine) INJECTION

Individual Healthcare Professional Authorisation

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professional.

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare Professional:- _____

is authorised to administer

ADRENALINE (Epinephrine) INJECTION

.....under this Patient Group Direction (NECSAT 2018/007)

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

Authorisation to use this PGD by: -

This above named healthcare professional has been authorised to work under this PGD by:

Name of Manager/Clinical Lead: - _____

Signature of Manager/Clinical Lead: - _____

Date signed: - _____

PGD Valid from: 1st Sept. 2018

Review Date: - May 2020

Expiry Date: - 31st August, 2020

Management & Monitoring of Patient Group Direction NECSAT 2018/007

ADRENALINE (Epinephrine) INJECTION

Healthcare Professional Authorisation (service/practice list)

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD

The following healthcare professionals are authorised to administer

ADRENALINE (Epinephrine) Injection under the Patient Group Direction (NECSAT 2018/007)

PGD Valid from date: 1st September 2018

PGD Expiry Date: 31st August 2020

Healthcare Professional			Authorised by:		
Name	Signature	Date	Name	Signature	Date

PGD Valid from: 1st Sept. 2018 | Review Date: - May 2020 | Expiry Date: - 31st August, 2020