SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Co-codamol Effervescent Tablets 8/500mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 8mg codeine phosphate hemihydrate and 500mg paracetamol

3 PHARMACEUTICAL FORM

Effervescent tablet
White circular, flat bevelled edge tablet, plain on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone.

For the treatment of muscular and rheumatic pains, headache, migraine, neuralgia, toothache and period pains.

This medicine contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It also contains paracetamol, another analgesic to relieve pain.

4.2 Posology and method of administration

For oral administration only. The tablets should be dissolved in at least half a tumbler of water before taking.

Adults and children over 15 years

One to two tablets dissolved in water every 4 to 6 hours as required, to a maximum of 8 tablets daily.

Children 12 to 15 years

One tablet dissolved in water every 4 to 6 hours when necessary to a maximum of 4 tablets in 24 hours.

Not recommend to children under 12 years of age

Elderly

There is no current evidence for the alteration of the adult dose except where there is impaired hepatic function when dosage reduction may be necessary.

Duration of treatment

Do not take more than 3 days continuously without medical review. The duration of treatment should be as short as possible, and if no effective pain relief is achieved the patients/carers should be advised to seek the views of a healthcare professional.

Treatment goals and discontinuation

Before initiating treatment with Co-codamol effervescent tablets, treatment duration and treatment goals, should be agreed together with the patient, in accordance with pain management guidelines. During treatment, there should be frequent contact between the physician and the patient to evaluate the need for continued treatment, consider discontinuation and to adjust dosages if needed. When a patient no longer requires therapy with codeine, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal. In absence of adequate pain control, the possibility of hyperalgesia, tolerance and progression of underlying disease should be considered (see section 4.4).

4.3 Contraindications

Conditions where morphine and opioids are contra-indicated e.g. acute alcoholism and where risk of paralytic ileus, acute respiratory depression, raised intracranial pressure or head injury (affects pupillary responses vital for neurological assessment).

Sensitivity to codeine or paracetamol or any of the constituents of the tablets.

In all paediatric patients (0-18 years of age) who undergo tonsillectomy and/or adenoidectomy for obstructive sleep apnoea syndrome due to an increased risk of developing serious and life-threatening adverse reactions (see section 4.4).

In women during breastfeeding (see section 4.6).

In patients for whom it is known they are CYP2D6 ultra-rapid metabolisers.

4.4 Special warnings and precautions for use

Other paracetamol containing medication should be avoided when taking co- codamol effervescent tablets. This medicinal product contains 438mg sodium per dose, equivalent to 22% of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 175% of the WHO recommended maximum daily intake for sodium. Co-codamol Effervescent Tablets are considered high in sodium. This sodium be particularly taken into account for those on a low salt diet.

The tablets contain aspartame and so should not be taken by patients with phenylketonuria. Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age.
Care should be observed in administering the product to any patient, whose condition may be exacerbated by opioids, including the elderly, who may be sensitive to their central and gastro-intestinal effects, those on concurrent CNS depressant drugs, those with prostatic hypertrophy, hypothyroidism and those with inflammatory or obstructive bowel disorders, Addison's disease or myasthenia gravis. Care should also be observed if prolonged therapy is contemplated.

Care should be taken when prescribing these tablets to patients with liver or renal impairment.

The hazards of paracetamol overdose are greater in those with non- cirrhotic alcoholic liver disease.

Concomitant administration with flucloxacillin
Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis or malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt

discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

The label will state:

Front of Pack

- Can cause addiction
- For three days use only

Back of Pack

- For the short term treatment of acute moderate pain when other painkillers have not worked. Do not take less than four hours after taking other painkillers.
- For the treatment of pain, including muscular and rheumatic pains, headache, migraine, neuralgia, toothache and period pains.
- If you need to take this medicine continuously for more than three days you should see your doctor or pharmacist
- This medicine contains codeine which can cause addiction if you take it continuously for more than three days. If you take this medicine for headaches for more than three days it can make them worse

The leaflet will state:

Headlines section (to be prominently displayed)

- This medicine can only be used for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone.
- You should only take this product for a maximum of three days at a time. If you need to take it for longer than three days you should see yourdoctor or pharmacist for advice.
- This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it.
- If you take this medicine for headaches for more than three days it can make them worse.

Section 1: What the medicine is for

- Co-codamol 8/500 is for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone. It is used to relieve muscular and rheumatic pains, headache, migraine, neuralgia (severe burning or stabbing pain following the line of a nerve), toothache and period pains.

Section 2: Before taking

- This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it.
- If you take a painkiller for headaches for more than three days it can make them worse.

Section 3: Dosage

- Do not take for more than 3 days. If you need to use this medicine for more than three days you must speak to your doctor or pharmacist.
- This medicine contains codeine and can cause addiction if you take it continuously for more than three days. When you stop taking it you may get withdrawal symptoms such as tremor, difficulty sleeping, feeling or being sick, sweating and increased heart rate, breathing or blood pressure. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

Section 4: Side effects

- Some people may have side-effects when taking this medicine. If you have any unwanted side-effects you should seek advice from your doctor, pharmacist or other healthcare professional. Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side-effects via the internet at **www.yellowcard.gov.uk**; alternatively you can call Freephone 0808 100 3352 (available between 10am-2pm Monday – Friday) or fill in a paper form available from your local pharmacy.

How do I know if I am addicted?

If you take the medicine according to the instructions on the pack it is unlikely that you will become addicted to the medicine. However, if the following apply to you it is important that you talk to your doctor:

- You need to take the medicine for longer periods of time.
- You need to take more than the recommended dose.
- When you stop taking the medicine you feel very unwell but you feel better if you start taking the medicine again.

Codeine is partially metabolised by CYP2D6. If a patient has a deficiency or is completely lacking this enzyme they will not obtain adequate analgesic effects. Estimates indicate that up to 7% of the caucasian population may have this deficiency. However, if the patient is an ultra-rapid metaboliser there is an increased risk of developing side effects of opioid toxicity even at low doses. General symptoms of opioid toxicity include nausea, vomiting, constipation, lack of appetite and somnolence. In severe cases this may include symptoms of circulatory and respiratory depression which may be life-threatening

and very rarely fatal. Estimates of prevalence of ultra-rapid metabolisers in different populations are summarized below:

Population	Prevalence %
African/Ethiopian	29%
African American	3.4% to 6.5%
Asian	1.2% to 2%
Caucasian	3.6% to 6.5%
Greek	6.0%
Hungarian	1.9%
Northern European	1%-2%

Post-operative use in children

There have been reports in the published literature that codeine given postoperatively in children after tonsillectomy and/or adenoidectomy for obstructive sleep apnoea, led to rare, but life-threatening adverse events including death (see also section 4.3). All children received doses of codeine that were within the appropriate dose range; however there was evidence that these children were either ultra-rapid or extensive metabolisers in their ability to metabolise codeine to morphine.

Children with compromised respiratory function

Codeine is not recommended for use in children in whom respiratory function might be compromised including neuromuscular disorders, severe cardiac or respiratory conditions, upper respiratory or lung infections, multiple trauma or extensive surgical procedures. These factors may worsen symptoms of morphine toxicity.

Risk from concomitant use of sedative medicines such as benzodiazepines or related drugs

Concomitant use of co-codamol and sedative medicines such as benzodiazepines or related drugs may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing with these sedative medicines should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe co-codamol concomitantly with sedative medicines, the lowest effective dose should be used, and the duration of treatment should be as short as possible.

The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers to be aware of these symptoms (see section 4.5).

Opioids can cause sleep-related breathing disorders including central sleep apnoea (CSA) and sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. In patients who present with CSA, consider decreasing the total opioid dosage.

Risks from concomitant use of opioids and alcohol

Concomitant use of opioids, including codeine, with alcohol may result in sedation, respiratory depression, coma and death. Concomitant use with alcohol is not recommended (see section 4.5).

Co-codamol should be used upon medical advice in patients with: • Mild-to-moderate hepatocellular insufficiency
• Severe renal insufficiency.

Monitoring after prolonged use should include blood count, liver function and renal function.

The leaflet will state in the “Pregnancy and breast-feeding” subsection of section 2 “Before taking your medicine”:

Usually it is safe to take Co-codamol 8/500 while breast feeding as the level of codeine in breast milk are too low to cause your baby any problems.
However, some women who are at increased risk of developing side effects at any dose may have higher levels of codeine in their breast milk. If any of the following side effects develop in you or your baby stop taking this medicine and seek immediate medical advice; feeling sick, vomiting, constipation, decreased or lack of appetite, feeling tired or sleeping for longer than normal, and shallow or slow breathing.

Hepatobiliary disorders
Codeine may cause dysfunction and spasm of the sphincter of Oddi, thus increasing the risk of biliary tract symptoms and pancreatitis. Therefore, codeine/paracetamol has to be administered with caution in patients with pancreatitis and diseases of the biliary tract.

As with other opioids, in case of insufficient pain control in response to an increased dose of codeine, the possibility of opioid-induced hyperalgesia should be considered. A dose reduction or treatment review may be indicated.

<u>Tolerance and opioid use disorder (abuse and dependence)</u>
Tolerance, physical and psychological dependence, and opioid use disorder (OUD) may develop upon repeated administration of opioids such as Co-codamol Effervescent Tablets. Repeated use of Co-codamol Effervescent Tablets can lead to OUD. A higher dose and longer duration

of opioid treatment can increase the risk of developing OUD. Abuse or intentional misuse of Co-codamol Effervescent Tablets may result in overdose and/or death. The risk of developing OUD is increased in patients with a personal or a family history (parents or siblings) of substance use disorders (including alcohol use disorder), in current tobacco users or in patients with a personal history of other mental health disorders (e.g. major depression, anxiety and personality disorders).

The patient should be made aware of the risks and signs of OUD as set out in the package leaflet. If these signs occur, patients should contact their physician.

For patients who experience signs and symptoms of OUD, and/or exibit drug seeking behaviours, review of concomitant opioids and psycho-active drugs (like benzodiazepines) and consultation with an addiction specialist may be required.

4.5 Interaction with other medicinal products and other forms of interaction

Avoid taking co-codamol effervescent tablets with CNS depressants or other paracetamol containing products. The speed of absorption of paracetamol may

be increased by metoclopramide or domperidone and absorption reduced by colestyramine. Opioid analgesics such as codeine antagonise the effects of domperidone or metoclopramide on gastrointestinal activity.

Co-administration with colestyramine may reduce absorption.

Concomitant administration with flucloxacillin
Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4)

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Concomitant administration of MAOI (e.g. tranylcypromine) can potentiate the central nervous effects and other side effects of unpredictable severity, Cocodamol should not be used within two weeks after the discontinuation of MAOI treatment.

Patients receiving other narcotic analgesics, antitussive, antihypertensives, antihistamines, antipsychotics, antianxiety agents or other CNS depressants (including alcohol) concomitantly with this codeine containing drug may exhibit additive CNS depression.

<u>Sedative medicines such as benzodiazepines or related drugs:</u>
The concomitant use of opioids with sedative medicines such as

benzodiazepines or related drugs increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dose and duration of concomitant use should be limited (see section 4.4).

Concomitant use of co-codamol effervescent tablets with gabapentinoids (gabapentin and pregabalin) may result in respiratory depression, hypotension, profound sedation, coma or death (see section 4.4).

Alcohol and opioids
The concomitant use of alcohol and opioids increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. Concomitant use with alcohol is not recommended (see section 4.4).

4.6 Fertility, Pregnancy and lactation

Pregnancy
A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Opioid analgesics may depress neonatal respiration and cause withdrawal effects in neonates of dependent mothers. There is a risk of gastric stasis and of inhalation pneumonia in mothers during labour.

Results of one case control study suggest that there might be an increased risk of malformations of the respiratory tract in the offspring of women who consumed codeine during the first four months of pregnancy. This increase was statistically not significant. Evidence of other malformations is also reported in epidemiological studies on narcotic analgesics, including codeine. Codeine has been used for many years without apparent ill consequence and animal studies have not shown any hazard

Patients should follow the advice of their doctor regarding the use of this product.

Lactation
Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

Codeine should not be used during breastfeeding (see section 4.3). Cocodamol Tablets 8/500mg are contraindicated during breast-feeding.

At normal therapeutic doses codeine and its active metabolites may be present in breast milk at very low doses and is unlikely to adversely

affect the breast fed infant.

However, if the patient is an ultra-rapid metaboliser of CYP2D6, higher levels of the active metabolites may be present in breast milk and on very rare occasions may result in symptoms of opioid toxicity in the infant, which may be fatal.

If symptoms of opioid toxicity develop in either the mother or the infant, then all codeine containing medicines should be stopped and alternative non-opioid analgesics prescribed. In severe cases consideration should be given to prescribing naloxone to reverse these effects.

4.7 Effects on ability to drive and use machines

Patients should be warned not to drive or operate machinery if they become dizzy or sedated while taking co-codamol effervescent tablets.

This medicine can impair cognitive function and can affect a patient's ability to drive safely.

This class of medicine is in the list of drugs included in regulations under 5a of
the Road Traffic Act 1988. When prescribing this medicine, patients should be told:
• The medicine is likely to affect your ability to drive
• Do not drive until you know how the medicine affects you
• It is an offence to drive while under the influence of this medicine
• However, you would not be committing an offence (called 'statutory defence') if:
- The medicine has been prescribed to treat a medical or dental problem and
- You have taken it according to the instructions given by the prescriber and in the
information provided with the medicine and
- It was not affecting your ability to drive safely

4.8 Undesirable effects

Co-codamol effervescent tablets are generally well tolerated but hypersensitivity reactions including skin rashes may occur. Rare cases of anaphylaxis, angioedema, urticaria, pruritus and fixed drug eruption have been reported with medications containing paracetamol and/or codeine. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to Co- codamol. High anion gap metabolic acidosis has been reported at an unknown frequency.

Codeine may sometimes cause typical opioid effects such as vomiting, constipation, nausea, light-headedness, dizziness,

confusion, drowsiness and urinary retention. The frequency and severity of these effects are determined by dosage, duration of treatment and individual sensitivity. Tolerance and dependence can occur, especially with prolonged high dosage of codeine. There have been rare reports of acute pancreatitis in patients taking codeine or codeine/paracetamol combinations.

- Regular prolonged use of codeine is known to lead to addiction and tolerance. Symptoms of restlessness and irritability may result when treatment is then stopped.
- Prolonged use of a painkiller for headaches can make them worse.

The information below lists reported adverse reactions, ranked using the following frequency classification:

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

System organ class	Frequency	Adverse reaction
Blood and lymphatic system disorders	Not known	Blood dyscrasias including thrombocytopenia and agranulocytosis
Immune system disorders	Not known	Hypersensitivity including skin rash may occur; anaphylactic shock, angioedema
Psychiatric disorders	Not known	Confusional state, dysphoria, euphoria, dependence
Nervous system disorders	Not known	Seizure, headache, somnolence, dizziness
Eye disorders	Not known	Miosis
Respiratory, thoracic and mediastinal disorders	Not known	Respiratory depression
Gastrointestinal disorders	Very rare	Pancreatitis
	Not known	Constipation, vomiting, nausea, dry mouth
Skin and subcutaneous tissue disorders	Very rare	Cases of serious skin reactions have been reported
Hepatobiliary disorders	Not known	Sphincter of Oddi dysfunction

Description of selected adverse reactions
High anion gap metabolic acidosis
Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low

glutathione levels in these patients.

Drug dependence
Repeated use of Co-codamol Effervescent Tablets can lead to drug dependence, even at therapeutic doses. The risk of drug dependence may vary depending on a patient's individual risk factors, dosage, and duration of opioid treatment (see section 4.4).

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

4.9 Overdose

Paracetamol
Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk factors

If the patient

a. Is on long term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
or
b. Regularly consumes ethanol in excess of recommended amounts.
or
c. Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia, and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, gastrointestinal bleeding and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N- acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS ora liver unit.

Further measures will depend on the severity, nature and course of clinical symptoms of paracetamol intoxication and should follow standard intensive care protocols.

Codeine

Nausea and vomiting are prominent symptoms of codeine toxicity, with circulatory and respiratory depression in severe overdose. The effects in overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs.

Symptoms

Central nervous system depression, including respiratory depression, may develop but is unlikely to be severe unless other sedative agents have been co- ingested, including alcohol, or the overdose is very large. The pupils may be pin-point in size; nausea and vomiting are common. Hypotension and tachycardia are possible but unlikely.

Management

This should include general symptomatic and supportive measures including a clear airway and monitoring of vital signs until stable. Consider activated charcoal if an adult presents within one hour of ingestion of more than 350 mg or a child more than 5 mg/kg.

Give naloxone if coma or respiratory depression is present. Naloxone is a competitive antagonist and has a short half-life so large and repeated doses

may be required in a seriously poisoned patient. Observe for at least four hours after ingestion, or eight hours if a sustained release preparation has been taken.

The opioid antagonist naloxone hydrochloride is an antidote to respiratory depression and must be administered intravenously.

Patients should be advised to first consult their healthcare professional before taking codeine if they are taking a benzodiazepine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Paracetamol combinations excl. psycholeptics
ATC Code: N02B E51

Paracetamol has antipyretic and analgesic actions with little anti-inflammatory effect. Codeine is an analgesic related to morphine but with only mild sedative effects.
Codeine exerts its effect through μ opioid receptors, although codeine has low affinity for these receptors, and its analgesic effect is due to its conversion to morphine. Codeine, particularly in combination with other analgesics such as paracetamol, has been shown to be effective in acute nociceptive pain.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Concentration in plasma reaches a peak in 30-60 minutes. Plasma half-life is 1-4 hours.

Paracetamol is relatively uniformly distributed throughout most body fluids, plasma protein binding is variable.

Codeine phosphate is well absorbed after oral administration and is widely distributed. About 86% is excreted in the urine in 24 hours; 40-70% if free or conjugated morphine, 5-15% is free or conjugated norcodeine.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydrogen carbonate, citric acid, sodium carbonate, povidone, simeticone, sodium saccharin, aspartame, polysorbate 80.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25ºC. Store in a dry place and protect from light.

6.5 Nature and contents of container

4 layer paper/PE/aluminium/PE blisters.

Pack sizes: 7, 10, 14, 20, 28, 30 and 32 tablets.

6.6 Special precautions for disposal

None

7. MARKETING AUTHORISATION HOLDER

Kent Pharma UK
Limited,
2nd Floor, Connect 38,
1 Dover Place,
Ashford, Kent,
England,
TN23 1FB.

8 MARKETING AUTHORISATION NUMBER(S)

PL 51463/0036

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/01/2025

10 DATE OF REVISION OF THE TEXT

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