NHS
Health Education England

Advisory Guidance

Administration of Medicines by Nursing Associates

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Foreword

I am delighted to introduce this advisory guidance which will support organisations who are training and employing Nursing Associates in a variety of settings. Ensuring patient safety and high-quality care is rightly at the centre of our policies and programmes; this Medicines Management guidance will thus play a key part in ensuring Nursing Associates, once qualified, will be able to work safely and appropriately as part of the nursing team.

This resource covers

- Education and training
- Organisational level policy
- Safety critical medications
- Administration of medicines via alternative routes
- Governance and assurance
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The guidance was developed over the past year by a Medicines Management Group convened by HEE, which included directors of nursing, pharmacists, the CQC, the Nursing and Midwifery Council, academics with pharmacy and safety expertise and a medical director.

It was reviewed in partnership with key partners in health and care to ensure its accuracy; these partners included NHS England, NHS Improvement, the Department of Health and Social Care, the Home Office and the MHRA.

I would like to extend my warmest gratitude to all of our partners who have been instrumental in producing these guidelines; and I hope that they will be helpful for employers, educators and trainees and provide assurance to patients and service users.

Professor Lisa Bayliss-Pratt
Chief Nurse and Interim Director for London and the South East

Background

Nursing Associates will become an essential part of the care and nursing workforce in England from 2019, providing high quality support to Registered Nurses.

As part of their training Nursing Associates will be educated to understand medicine management and, within the confines of local employer policies, administer prescribed medicines safely and appropriately. It is essential that Nursing Associates are trained to be competent in the relevant components of this area so that they can make a full contribution to the provision of effective care to the public and patients in primary, acute, secondary, community and social care settings – a vast care landscape.

The Nursing Associate role will be regulated under statute, which will legally establish a register of qualified practitioners and provide assurance of high education and training standards, including competence to administer prescribed medicines safely.

Alongside the forthcoming Nursing and Midwifery Council's (NMC) regulatory standards for the role, HEE is publishing supplementary guidance to provide clarity to all NHS organisations about how Nursing Associates could be deployed to administer medicines safely and effectively.

Purpose

This guidance was produced by a specially convened Health Education England (HEE) Medicines Management Group.

Its purpose is to assist trainee Nursing Associates when receiving medicines management training, and to guide employers in delivering medicines management training to trainee Nursing Associates. This will help support safe and effective medicines management practice by Nursing Associates. It is intended to clarify their remit for Nursing Associates and reassure the public of the Nursing Associate role in relation to medicines management.

This document should be read in conjunction with:

i) Health Education England's Nursing Associate Curriculum Framework[1]. The Curriculum Framework supports national consistency and coherence in the delivery of the education and training model for Nursing Associates. This includes the education and training of Nursing Associates in relation to Medicines Management.

ii) The Nursing and Midwifery Council's (NMC) draft Nursing Associate Regulatory Standards, and when published, the NMC's Nursing Associate Regulatory Standards.

[1] https://hee.nhs.uk/sites/default/files/documents/Nursing%20Associate%20Curriculum%20Framework%20Feb2017_0.pdf

This interim guidance includes recommendations on:

- Education and training
- Organisational level policy
- Safety critical medications
- Administration of medicines via alternative routes
- Governance and assurance.

Who is it for?

- Employers of Nursing Associates
- Trainers/educators of Nursing Associates
- Supervisors of Nursing Associates
- Commissioners of Nursing Associate training programmes
- Prospective Nursing Associates
- People cared for by Nursing Associates.

Section 1: Development of this guidance

Key terms

1.1 This document applies to the administration of medicines by trainee and regulated Nursing Associate professionals.

1.2 The Medicines Management Group has made seven recommendations for Nursing Associate employers, the Nursing and Midwifery Council (NMC) and HEE. These recommendations constitute this guidance.

1.3 In all instances, the guidance in this document is supplementary to, and is subject to, any locally arranged medicines practices or guidance agreed in respect of Nursing Associates.

Statutory regulation of the role

1.4 In January 2017, the Nursing and Midwifery Council agreed to the Secretary of State for Health's request to become the regulator for the Nursing Associate role.

1.5 The NMC's role as a regulator will set the standards of proficiency for the nursing associate. These will be minimum standards that will need to be achieved by all trainee nursing associates in order to join the NMC register. The NMC will consult on these draft standards in 2018 and have indicated that identified routes of medicines administration will be included. It is planned for the standards to be finalised and released in October 2018 following consultation and agreement by Council.

Therefore the Nursing Associate, as a registrant, will be accountable for their actions, required to continue to meet the standards of proficiency and will be subject to the regulatory functions of the NMC.

Curriculum Framework

1.6 Following a national consultation and a series of consensus building workshops focussing on the skills, parameters and associated risk of introducing the new Nursing Associate role, Health Education England, in partnership with Skills for Health and Skills for Care, developed the Nursing Associate Curriculum Framework[2]. This was published in October 2016.

1.7 The Curriculum Framework provides a benchmark for all Nursing Associate training providers to deliver programmes to equip Nursing Associates with the breadth of skills and professional competence to support Registered Nurses and other professionals to deliver high quality care. This competence includes educating and preparing Nursing Associates to understand and undertake all types of medicines administration, including activity concerning routes and contraindications.

[2] https://hee.nhs.uk/sites/default/files/documents/Nursing%20Associate%20Curriculum%20Framework%20Feb2017_0.pdf

1.8 HEE consulted with stakeholders in the production of the Framework, and the issue of medicines management was frequently raised as one in need of further development. It is this feedback that has led the development of this guidance. The Nursing Associate Curriculum Framework[3] also states that it is "…*an essential requirement for Nursing Associates to be trained and competent in this area*."

1.9 Patient safety remains the priority when developing this new role. Page nine of the Nursing Associate Curriculum Framework states:

f) The following areas are deemed beyond the parameters of practice for the nursing associate role: This is not an exhaustive list.

viii) Administer medicines under a patient group directive

ix) Nursing associates will not prescribe medicines.

1.10 This guidance aligns with this statement and is intended to expand and clarify Curriculum Framework content.

1.11 The training and education of Nursing Associates in relation to medicines management is also covered under Domain 3 (Delivering Care) of the Curriculum Framework. Under Clinical and Care Skills 6, trainee Nursing Associates will be trained to correctly and safely undertake delegated medicine calculations, and to administer medicines safely and in a timely manner.

1.12 While it is for employing organisations to determine whether Nursing Associates administer medicines in their service and the extent of that role, all trainee Nursing Associates will need to demonstrate proficiency in medicines administration, in line with the Curriculum Framework and the NMC standards of proficiency, to achieve qualification.

1.13 The prospective role of a Nursing Associate in the administration and management of medicines was also one of the reasons most commonly given in support of regulation of the role. The Secretary of State's decision to regulate the role will allow the chosen regulator (the NMC) to develop the standards of proficiency for the Nursing Associate role, which will include the standards for medicines management. The NMC will pick up and continue these discussions in the process of developing its regulatory standards for the role.

1.14 However the success of the Nursing Associate training rollout, and the faster than anticipated pace of development of the role, is leading participatory organisations such as HEE to address issues earlier and as they arise. Developed thinking around safe and effective medicines management by Nursing Associates falls into this category.

Section 2: Recommendations

2.1 The following recommendations are made by HEE's specifically created Medicines Management Group; a time-limited Group specially created for this project. The recommendations support employers in safe and effective deployment of regulated Nursing Associates in medicines management activity.

[3] https://www.hee.nhs.uk/sites/default/files/documents/Curriculum%20Framework%20Nursing%20Associate.pdf

2.2 The promotion of self-care and the safe self-administration of medicines are accepted as fundamental principles for the education and training of Nursing Associates. These principles underpin these recommendations.

Trainee Nursing Associates

Recommendation 1:
Employing organisations should ensure adequate levels of supervision are in place to support trainee Nursing Associates in the education and training of medicines management, and these supervision levels should be clearly stated in any local medicines policy (where such a policy exists).

It is essential that trainee Nursing Associates receive adequate practice experience, education, training, supervision and support to achieve the standards of proficiency associated with medicines management during their two-year programme. While there was some scrutiny with regard to the level of knowledge detailed in the Curriculum Framework, there was universal agreement among the membership of the Group on the need to demonstrate competence prior to completing the programme.

Recommendation 2:
The Nursing and Midwifery Council should ensure the following core routes of medicines administration are included by name in the Nursing Associate standards of proficiency:

- Oral
- Topical[4]
- Subcutaneous
- Per rectum
- Inhaled

While it will be the decision of the employer as to whether Nursing Associates administer medicines in their service and the extent of that role, all trainee Nursing Associates will need to demonstrate the proficiencies for medicines administration set out in the NMC's standards of proficiency, required to join the register.

Regulated Nursing Associates

Recommendation 3:
Employing organisations should take appropriate steps to assure themselves and the CQC that practicing Nursing Associates have the qualifications, competence, skills and experience to undertake the activities required of them.

As with any medicines management policy, reporting patient safety and safeguarding incidents will occur at a local, organisational and national level.

Nursing Associates will be regulated and therefore subject to the same fitness to practice expectations as any other registrant regulated by the NMC. The CQC will expect Nursing Associates to comply with the standards and codes of practice of their professional body in the same way that they do for all other regulated professions.

[4] Topical referring to the application of a drug to a site where it is intended to have its effect e.g eye, outer ear, nasal passages, skin preparations, transdermal patches, inhaled drugs

The CQC expects service providers to demonstrate that their healthcare staff have the requisite and approved qualifications, competence, skills and experience to undertake all functions associated with their employment role, including the administration of medicines if appropriate. This will include Nursing Associates, once regulated.

Recommendation 4:
Employers should maintain an appropriate local policy to guide all parties in the remit, responsibilities and activities regulated Nursing Associates are expected to perform in the execution of their duties with regards medicines management of patients. This policy should cover:

- Ordering medicines
- Receiving medicines
- Verbal orders (in particular in social care and community settings) [5]
- Safe storage and disposal of medicine
- Administering As Required/PRN medication.

When creating this recommendation, consideration was given to the fact that in the social care sector, some medicines management (including administration of medicines) is routinely performed by unregulated care staff. Best practice guidance around this is available[6] [7], including prompts to employers to consider the appropriateness of medicines management tasks for specific roles[8].

Recommendation 5:
Employing organisations that expect Nursing Associates to administer medicines should name any safety critical medicines to be administered by Nursing Associates in their organisation (in addition to any medicines identified as Controlled under the Misuse of Drugs legislation) and ensure that local policies aligned to national guidance exist to mitigate risks.

Within each of the recommended routes of administration, there are medicines that carry a higher risk of harm (sometimes referred to as safety critical medicines). Examples of these medicines include methotrexate, warfarin, insulin, digoxin, lithium and opioids; medicines used outside of their licensed indication (off-label), and recently licensed Black Triangle medications.[9]

While Nursing Associates should not be precluded from administering these medicines, caution should be exercised to overtly promote a patient safety culture.

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[5] In the majority of settings, verbal orders are no longer given. However if verbal orders are permitted through relevant local policy, then clear guidance for Nursing Associates should be given.

[6] http://psnc.org.uk/sheffield-lpc/wp-content/uploads/sites/79/2013/06/carehomesprnguidance.pdf

[7] http://www.windsorascotmaidenheadccg.nhs.uk/download/care_home_guidance/11.%20Good%20Practice%20Guidance%2011.%20'when%20required'%20(PRN)%20medication.pdf

[8] An example of this in relation to As Required medicines.

- *Do your care plans provide detailed information on medication prescribed as 'when required'?*
- *Does your medication policy cover the administration of 'when required' medication?*
- *Is 'when required' medication regularly given? If so has a review of the medication taken place?*
- *Are 'when required' medicines held in suitable quantities and checked to be in date?*

[9] Black Triangle medicines are medicines or vaccines that are either new to market, or being used off-licence.

Upon publication of the Curriculum Framework, questions were asked concerning Nursing Associates administering Controlled Medicines. The Medicines Management Group discussed this at length, with some sector representatives (care home, hospice, community services) providing comparable examples of how this is already occurring within their settings.

The Group and provider feedback highlighted that this is a complex area. The risk of administration of medicines to patient safety heightens depending on the route of administration, not purely on the medicine itself. It was therefore decided that the focus should be on organisations being aware, and providing assurance, in regard to safety critical medicines rather than focusing purely on medicines identified as Controlled under the Misuse of Drugs legislation.

However to note: legally a Nursing Associate may administer a Schedule 2[10], 3[11] or 4[12] medicine under the Misuse of Drugs Regulations 2001, provided they are acting in accordance with the directions of an appropriately regulated prescriber i.e. in accordance with the directions of a doctor, dentist, a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, a registered nurse/pharmacist/ physiotherapist/chiropodist independent prescriber (within their prescribing authority).

Recommendation 6:
Employing organisations expecting Nursing Associates to administer medicines via additional routes[13] should ensure any administration is covered in a robust organisational policy. This policy should:

- define these additional routes
- help assure that administration by the specific route is in the best interest of the patient
- assess the associated levels of risk from administration by each route
- clearly state the threshold standard of competency required for each administration route
- outline the necessary education and training for administration by these routes (available to Nursing Associates)
- state how this training is formally assessed and when re-assessment should occur
- provide clear lines of delegation and accountability for any administration

Some services may require that regulated Nursing Associates administer medicines via additional routes, for example enteral or intramuscular. Where this occurs, the Group believe such activity should only be carried out when an organisational policy addressing Nursing Associates and additional routes is already in place.

Recommendation 7:
HEE should work with employers and NHS England to develop proposals for nursing associates to be able to supply and administer medicines using Patient Group Directions (PGDs).[14]

[10] http://www.legislation.gov.uk/uksi/2001/3998/schedule/2/made
[11] http://www.legislation.gov.uk/uksi/2001/3998/schedule/3/made
[12] http://www.legislation.gov.uk/uksi/2001/3998/schedule/4/made
[13] HEE is defining 'additional routes' as any routes not listed as 'core routes' under Recommendation 2.
[14] This would require a change to legislation and require public consultation.

A PGD is a written instruction for the supply or administration of medicines to certain groups of patients by a named health professional. The instruction must be agreed and signed by a senior doctor and pharmacist, and include detailed information including the name of the professional who can supply or administer the medicine(s); the description, class, dosage and strength of the medicines to be supplied or administered; and the condition or clinical criteria for which a patient is eligible for treatment under the PGD.

Only regulated professions are able to supply or administer medicine under a PGD, and ministers are responsible for making decisions about whether legislation should be amended to allow professions to supply or administer medicines through a PGD in the future.

Providers consider Nursing Associates should be able to administer some medicines under PGDs as this would be advantageous to patient care without compromising on safety. Examples of this include immunisations as part of a national programme (for example the influenza vaccine) and - upon completion of competency - using a saline flush following the insertion of a cannula.

Currently Nursing Associates, as a new profession, are not on the list of professions lawfully allowed to administer medicines under a PGD. (However, there is an equivalent level role - dental hygienist - on the allowed professions list).

Nursing Associates cannot be added to this list until they become a regulated role. Once regulated, a Case of Need[15] would need to be made by NHS England through the Department of Health Non-Medical Prescribing Board, to seek agreement from Ministers for a public consultation. The results of a public consultation would then need to be submitted to the Commission on Human Medicines (CHM), who would make recommendations to Ministers regarding any changes to legislation.

Section 3: Governance and Assurance

3.1 In addition to the legal framework of The Human Medicines Regulations 2012, the Medicines Management Group discussions identified three tiers of governance structures and system-wide levels of assurance to support safe medicines management by Nursing Associates.

3.2 **Tier 1: The Nursing Associate as a prospective regulated, registered professional**

The NMC's role as a regulator will set the standards of proficiency for the nursing associate. These will be minimum standards that will need to be achieved by all trainee nursing associates in order to join the NMC register. The NMC will consult on these draft standards in 2018 and have indicated that identified routes of medicines administration will be included. It is planned for the standards to be finalised and released in October 2018 following consultation and agreement by Council.

Therefore, the Nursing Associate, as a registrant, will be accountable for their actions, and any delegatory arrangements, and will be subject to the regulatory functions of the NMC.

[15] A Case of Need would outline the clinical case for extending prescribing rights to the Nursing Associate profession. The Case of Need would likely focus on improving quality of care for patients in relation to safety, clinical outcomes and experience, and improving efficiency of service delivery and value for money.

Tier 2: The employer organisation

The employer has a responsibility to govern the role of the Nursing Associate through their employment governance structures. If they require Nursing Associates to administer medicines using routes not within NMC standards of proficiency, employers will need to mitigate against potential risk by using locally agreed education, training, policy and protocols.

Tier 3: System wide assurance

There are system-wide organisations with statutory and regulatory responsibilities for ensuring the safety and quality of services, including the CQC and NHS Improvement.

Care Quality Commission (CQC) inspection teams use Key Lines Of Enquiry (KLOE) and associated prompts as a framework to assess services. Since Autumn 2017, the CQC has deployed two sets of KLOE; one for all healthcare providers [16] and one for all providers of adult social care[17].

The CQC is also responsible for enforcing Regulation 12 (Safe care and treatment) of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

The CQC expects Nursing Associates to have the qualifications, competence, skills and experience to undertake their employed role. Once a regulated profession, the CQC will expect Nursing Associates to comply with the standards and codes of practice of their regulator (in this case the NMC) as per all regulated healthcare roles.

Section 4: Remit of HEE's Medicines Management Group

4.1 HEE established a Medicines Management Group to develop this guidance and formulate the recommendations within it. The Medicines Management Group was cross-sector, drawing membership from health and care providers as well as system experts. A list of the group's membership is published as Appendix 1.

4.2 The purpose of the group was to:

1. Outline current medicines administration practice and guidance, nationally and internationally.

2. Explore any safety concerns around medicines administration by Nursing Associates.

3. Develop guidance to support organisations who employ regulated Nursing Associates on the administration of medicines.

[16] http://www.cqc.org.uk/sites/default/files/20170609_Healthcare-services-KLOEs-prompts-and-characteristics-FINAL.pdf
[17] http://www.cqc.org.uk/sites/default/files/20170609_Adult-social-care-KLOEs-prompts-and-characteristics-FINAL_2.pdf

4.3 Key discussions by the medicines group included:

1. Should Nursing Associates be able to administer medicines via all routes or via named routes?

2. Should the developing NMC Nursing Associate standards of proficiency focus on a prescribed list of medicines rather than routes of administration?

3. How can organisational policy be utilised to mitigate risk if a service requires a Nursing Associate to administer medicines or to use routes of administration that are beyond the regulated standards of proficiency?

4. How to manage the priority of patient safety, at the same time as developing the parameters of the Nursing Associate role to meet service needs. Some sector leads raised concern that if the role of the Nursing Associates in regard to medicines administration was too restricted then the role would not be utilised.

4.4 The group met three times and this guidance is a result of its efforts. At the final meeting of the group the following recommendations were agreed as appropriate guidance to support organisations who are currently part of the Nursing Associate test sites and well as those who will seek to employ registered Nursing Associates in the future.

Section 5: Existing guidance and similar practice

5.1 Following the Medicines Management Group's first meeting, HEE commissioned Surrey & Sussex Library and Knowledge Services to conduct a literature search, to examine what existing guidance was available for non-regulated roles in medicine administration in England and elsewhere. The results of this literature search are in Appendix 2. This following section provides a summary of some of the guidance available.

5.2 Under the general rules of the Human Medicines Regulations 2012, prescription-only medicines can only be given in accordance with the directions of an appropriate practitioner for a named patient. Appropriate practitioners include doctors, dentists, nurse and pharmacist prescribers. Appropriate practitioners also include supplementary prescribers who can prescribe within the terms of a patient-specific clinical management plan.

5.3 The Human Medicines Regulations 2012 includes exemptions from these restrictions for certain groups of registered health professionals to supply or administer certain medicines on their own initiative. For example, paramedics treating sick or injured people or a midwife administering perinatal medicines.

5.4 The Human Medicines Regulations 2012 also lists parenteral medicines, known as Schedule 19 medicines, that may be administered by anyone for the purpose of saving a life in an emergency (these are listed in Appendix 2). Nursing Associates, in line with any other healthcare professional, will be able to administer medicines on this list in order to save a life. Individual trusts may have local protocols in place to support healthcare professionals covered under Schedule 19. These may provide dosing instructions and define the circumstances in which the medication should be administered.

England

5.5 In 2016 the Department of Health released a good practice guide for the 'Safe administration of medicines in care homes by care assistants'[18]. This guidance provides information for care home providers, managers and staff on the administration of prescribed medicines for a named individual by care assistants, as well as the requirements for safety and quality assurance. The guidance also outlines the role of the registered nurse if care assistants are administering medicines in care homes with nursing provision.

Scotland

5.6 In March 2015, Scotland's Care Inspectorate published the 'Prompting, assisting and administration of medication in a care setting: guidance for professionals''.[19] This states that staff in care settings should be able to identify the difference between prompting, assisting and administering medicines.

Wales

5.7 In November 2015. an All Wales strategy group released 'All Wales Guidance for Health Boards/Trusts in Respect of Medicines and Health Care Support Workers'[20]. This guidance is directed at all healthcare support workers (including midwifery assistants and nursery nurses) employed by Health Boards and Trusts in Wales.

Northern Ireland

5.8 There is no comparable guidance available, as the administration of medicines is not a delegated task.

Canada and Australia

5.9 In both Canada and Australia, the registered nurse and their Nursing Associate equivalent role (Registered Practical Nurse in Canada and Enrolled Nurse in Australia) have the same education, training and parameters of practice regarding medicines administration.

5.10 In Australia, enrolled nurses who are competent to administer medicines hold a specific notation on the register. This indicates that they have undertaken specific medication education.[21]

[18] https://www.gov.uk/government/publications/administration-of-medicine-in-care-homes

[19] http://www.careinspectorate.com/images/documents/2786/prompting-assisting-and-administration-of-medication-in-a-care-setting-guidance-for-professionals.pdf

[20] http://www.awmsg.org/docs/awmsg/medman/All%20Wales%20Guidance%20for%20Health%20Boards%20and%20Trusts%20in%20Respect%20of%20Medicines%20and%20HCSWs.pdf

[21] http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/FAQ/Enrolled-nurses-and-medicine-administration.aspx

Appendix 1: Membership of the Medicines Management Group

Name	Organisation and Position
Dr Richard Adams	Chief Nurse Bupa UK
Professor Lisa Bayliss-Pratt	Chief Nurse and Interim Regional Director for London and the South East Health Education England
Jane Connor	Talent for Care Lead Health Education England North Central and East London
Avril Devaney	Director of Nursing, Therapies and Patient Partnership Cheshire and Wirral Partnership NHS Foundation Trust
Samantha Donohue	Senior Nurse Manager: Policy Health Education England
Liz Gormley-Fleming	Head of Department for Nursing and Social Work University of Hertfordshire
Kenye Karemo	Deputy Director of Nursing Barking, Havering and Redbridge University Hospitals NHS Trust
Tina Kenny	Medical Director Buckinghamshire Healthcare NHS Trust
Alison Lee	Managing Director Woodlands and Hillbrow Care Homes Ltd
Professor Cheryl Lenney	Chief Nurse Central Manchester University Hospitals NHS Foundation Trust
Frank Milligan	Senior Lecturer in Patient Safety University of Bedfordshire
Carolyn Morrice	Chief Nurse and Director of Patient Care Standards Buckinghamshire Healthcare NHS Trust
Robin Offord	Director of Pharmacy University College London Hospitals
Professor David Sines	Chair of the Medicines Management Group Emeritus Professor and Independent Healthcare Consultant Buckinghamshire New University

Elaine Tolliday	Clinical Director Keech Hospice (Bedfordshire)
Geraldine Walters CBE	Director of Nursing and Midwifery Nursing and Midwifery Council
Geraldine Yates	Regional Medicines Manager Care Quality Commission

Appendix 2: List of Schedule 19 Exemptions

To be administered by anyone for the purpose of saving a life in an emergency:

- Adrenaline 1:1 000 up to 1 mg for intramuscular use in anaphylaxis
- Atropine sulphate and obidoxime chloride injection
- Atropine sulphate and pralidoxime chloride injection
- Atropine sulphate injection
- Atropine sulphate, pralidoxime mesilate and avizafone injection
- Chlorphenamine injection
- Dicobalt edetate injection
- Glucagon injection
- Glucose injection
- Hydrocortisone injection
- Naloxone hydrochloride
- Pralidoxime chloride injection
- Pralidoxime mesilate injection
- Promethazine hydrochloride injection
- Snake venom antiserum
- Sodium nitrate injection
- Sodium thiosulphate injection
- Sterile pralidoxime

Correct as of December 2017.