

## Resolution CM/Res(2016)2

### on good reconstitution practices in health care establishments for medicinal products for parenteral use

*(Adopted by the Committee of Ministers on 1 June 2016  
at the 1258th meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50),<sup>1</sup>

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, among others, by common action in the public health field including the adoption of common regulations;

Having regard to the standard-setting carried out under the Convention on the Elaboration of a European Pharmacopoeia and its Protocol (ETS No. 134), which endeavours to promote progress in every way possible, both in the social field and the related field of public health through the harmonisation of requirements for medicinal products, which are of great importance to the peoples of Europe;

Recalling also the chapters and monographs of the European Pharmacopoeia containing general and specific requirements applicable to medicinal products, in particular about standards and methods for the control of the chemical, pharmaceutical and microbiological quality of active substances and excipients, about dosage forms and containers;

Underlining the need to apply where required, national and European legislation in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 and where possible relevant international standards such as those developed by the World Health Organization and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S);

Bearing in mind the provisions included in Committee of Ministers' Resolution CM/ResAP(2011)1 on the quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients, in particular, comprising in section 9, *inter alia*, a set of recommendations to the relevant authorities to establish new regulations or to revise existing regulations in the field of reconstitution and related activities and urging the need to implement them;

Considering that medication errors including those involving the reconstitution of a medicinal product into a dosage form that is ready to be used or administered to a patient, and quality defects associated with inappropriate reconstitution, have serious implications for patient safety, in particular in the case of parenteral administration;

Noting that sufficiently detailed practical information is not always available for the reconstitution of a medicinal product into a ready-to-use or administered dosage form, to ensure compliance with the marketing authorisation and the information approved by medicines regulatory authorities;

Emphasising that patient safety should be at the centre of health care and associated interventions, and that health professionals should be supported by appropriate guidance to prevent risk of health damage caused by inappropriate reconstitution in health care establishments in Europe;

Noting that the reconstitution of medicinal products in health care establishments is not harmonised throughout Europe and falls under the national competencies of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia;

<sup>1</sup> States concerned: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine and United Kingdom.

Recalling that the health care establishment's decision as to where reconstitution should take place should be based on an assessment of the entailed risk, which should give rise to appropriate follow up including the necessary support to professionals in health care;

Emphasising that a pre-requisite of safe reconstitution is the appropriate training of health professionals such as pharmacists and nurses in line with national professional regulation or example as regards aseptic working methods;

Underlining that the development and adherence to standards for the quality and safety of medicinal products that require reconstitution before use or administration to a patient, in addition to the relevant pharmacopoeia requirements, are necessary for ensuring appropriate patient safety in Europe and the efficacy of pharmacotherapy;

With a view to preventing health damage in patients caused by incorrect reconstitution, and to provide the responsible national authorities with model approaches for supporting health care management and health professionals involved, to plan and carry out reconstitution, recommends that the governments of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia adapt their regulations in accordance with the provisions set out in the present resolution, including its appendix, pertaining to the:

- responsibilities;
- minimum requirements (standards) for reconstitution;
- handling of risks posed by reconstitution.

#### *Appendix to Resolution CM/Res(2016)2*

### **1. Field of application**

This resolution covers medicinal products for human use only. It should guide the health care establishment's decision as to where reconstitution should take place: in a pharmacy or the clinical area. This decision should be based on a risk assessment (see sections 4 and 5) and support professionals in health care establishments, such as pharmacists, nurses etc., in their planning and carrying out of reconstitution.

This resolution applies to the reconstitution of medicinal products for parenteral administration which are administered to patients of the given health care establishment.

Its provisions should be also applied if medicinal products for parenteral administration supplied by a pharmacy are not "ready to administer" (RTA) and further handling is required in the clinical area and in community settings for example in institutional care such as in homes for the elderly. The provisions are not primarily aimed at practices for reconstitution in pharmacies and should by no means substitute specific requirements for these.

Outside the scope of this resolution are:

- the reconstitution of medicinal products intended for distribution to another health care establishment;
- the administration of a reconstituted medicinal product to a patient;
- the reconstitution of radiopharmaceuticals.

### **2. Definitions**

Diluent for reconstitution or for infusion: a solvent appropriate for reconstitution of a medicinal product, such as Water for Injection, or Sodium Chloride 0.9% Injection.

Medication error: any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to: professional practice, health care products, procedures and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education and monitoring of patients; and use.

Aseptic handling: a procedure to enable sterile medicinal products to be made ready to administer, using closed systems.

Aseptic *non-touch* technique (ANTT): a procedure where the practitioner (operator) avoids touching key elements of a piece of equipment, such as the tip of a needle or the inside of a sterile dressing.

Parenteral manual (syn.: Injectable medicines guide): a document or database explaining how to handle medicinal products that are administered parenterally. Apart from other more therapy-related information, it deals with the reconstitution of medicinal products including dissolution, dilution in infusion bags or syringe pumps, (in)compatibilities with other medicines and adverse reactions.

Closed-system procedure for sterile medicinal products: a procedure whereby a sterile medicinal product is prepared by transferring sterile starting materials or solutions to a pre-sterilised sealed container, either directly or by using a sterile transfer device, and without exposing the solution to the external environment (such as intravenous infusion services: services for cytotoxic medical products).

Ready to administer (RTA): a presentation of the medicinal product at the required concentration and volume, in the final container (syringe, infusion bag or elastomeric device), and ready to be administered to the patient.

Open-system procedure for sterile medicinal products: a procedure whereby a sterile medicinal product is prepared and the solution is exposed to the external environment.

Ready to use (RTU): a presentation of the medicinal product at the required concentration in a container. The required volume is transferred to a final administration device (syringe, infusion bag or elastomeric device) for administration to the patient.

Reconstitution: manipulation to enable the use or administration of a medicinal product for products with a marketing authorisation issued by any competent medicines regulatory authority, the reconstitution is carried out in accordance with the instructions given in the summary of product characteristics (SmPC) or the package leaflet.

Clinical areas: areas in health care establishments where patients receive treatment, such as wards, ambulatory care settings and operating theatres.

### **3. Responsibilities**

#### *3.1 Authorities*

National authorities should develop, in co-operation with all relevant stakeholders such as the relevant professional bodies, specific legislation and guidance on reconstitution. A national parenteral manual developed in co-operation with relevant professionals is recommended.

#### *3.2 Health care establishment*

##### *3.2.1 Management*

It is the responsibility of the management to ensure systems are in place for safe reconstitution. This responsibility includes provision of the necessary resources required for safe reconstitution of parenterals, for example personnel, premises, equipment, and work contracted out.

The managing board of the health care establishment should decide and document which medicinal products should be reconstituted in pharmacy and which medicinal products can be safely reconstituted in clinical areas based on a risk assessment (see sections 3.3 and 5).

If the minimum standards for the reconstitution in clinical areas are not kept (see sections 4 and 5), the health care establishment management should ensure that parenteral medicinal products are appropriately reconstituted elsewhere and available in such cases, e.g. by preparation in a pharmacy or by purchasing as RTA products.

The residual risk with the chosen risk reduction methods in place should be acceptable to the health care establishment. If the risk remains high, then the health care establishment may consider it appropriate to record the specific item on their organisation's risk register and the health care establishment management should ensure that parenteral medicinal products are appropriately reconstituted elsewhere and available in such cases, e.g. by preparation in a pharmacy or by purchasing as RTA medicinal products.

It is the responsibility of the health care establishment management to ensure that a risk review of reconstitution practice is regularly undertaken and to consider the results of each review in the context of their own organisation.

The health care establishment management should authorise the parenteral manual.

### 3.2.2 *Designated person*

The designated person should have a clear mandate and direct access to the health care establishment management. A designated person should be appointed in each health care establishment to be responsible for the quality of reconstitution (procedure), wholly or as part of other functions. In practice, a reconstitution team co-ordinated by the designated person may be created. The responsibility of the designated person includes the approval of the decision as to which products are suitable for reconstitution in specific clinical areas.

The designated person should develop a quality management system for reconstitution, including preparing documentation and ensuring training of personnel involved in reconstitution.

When reconstitution takes place in clinical areas, the designated person should approve standard operating procedures and ensure that the personnel involved in reconstitution are appropriately trained.

The designated person should preferably be a pharmacist, but if not they should be of suitable training and have an appropriate experience to perform this role.

The parenteral manual is for example prepared by the hospital pharmacist in cooperation with the medical and non-medical team (such as pharmacists, physicians, nurses, pharmacy technicians) and is relevant to the scope of this resolution in relation to the reconstitution of medicinal products for parenteral administration. It should be available in the pharmacy and the clinical areas of the health care establishment.

The manual should contain the following information: reconstitution advice on medicinal products, including at least appropriate diluents and concentrations, the administration route, the rate and duration of administration, compatibilities, incompatibilities with other medicinal products, usual diluents, containers and maximum and minimum physico-chemical stability of the active pharmaceutical ingredients when diluted. The leaflet authorised by the regulatory authority may be included in the parenteral manual.

The primary sources of information on medicinal products' reconstitution in the parenteral manual are the authorised label and leaflet; in practice there may be a need for further or more detailed reconstitution information beyond that which is covered by the label, leaflet and SmPC.

### 3.2.3 *Personnel in clinical areas*

The qualifications and competence (continuous education, maintaining competence, regular training) of all personnel involved in reconstitution should be documented to comply with the requirements described in the quality management system. Knowledge and skills in calculation, hygiene and microbiology, and training in aseptic handling techniques are particularly important.

## 3.3 *Risk Assessment*

A risk assessment for the reconstitution of each medicinal product should be performed in the health care establishment taking into account the most relevant risk factors (see sections 4 and 5). Prospective and retrospective risk analysis and auditing are some useful methods that may yield divergent views on risks in hospitals. Since all these methods may have their bias, their combined use provides managers with a more complete and balanced picture of risks.

Following the risk assessment discussed above, a hierarchy of medicinal products, ranked in order of their reconstitution risk, should be established for the specific health care establishment. Based on this hierarchy, the managing board of the health care establishment should decide and document which medicinal products should be reconstituted in a pharmacy and which medicinal products can be safely reconstituted in clinical areas. This hierarchy should be regularly reviewed and risks reassessed (see section 5). When reconstitution takes place in clinical areas, the designated person should approve standard operating procedures and ensure that the personnel involved in reconstitution are appropriately trained.

The manager of the clinical area and the designated person should oversee the risk assessment, sign both the assessment (see Note: "Checklist for the identification, assessment and reduction of risk posed by the

reconstitution of medicinal products in clinical areas; in short “Checklist”) and forward the assessment to the management board of the health care establishment for decision.

### 3.4 Auditing

Regular auditing, preferably internal audits, of all activities associated with parenteral medicinal products in health care establishments is required (suggested annually) as a means of improving the reconstitution procedure (see section 5).

Training of personnel in performing audits (self-inspection) enhances their awareness and understanding in relation to the patient safety implications of activities involving medicinal products for parenteral administration.

## 4. Minimum requirements (standards) for reconstitution

The quality system in the clinical area needs to encompass reconstitution. Particular attention should be given to ensuring that the following issues are comprehensively addressed in a document that is available to the personnel involved:

- an overall procedure for reconstitution that covers general aspects such as aseptic handling, hygiene, any special clothing requirements; policy on independent checking, requirement to use immediately etc.;
- detailed instructions for the safe reconstitution of each medicinal product e.g. the leaflet authorised by the regulatory authority (Parenteral manual, see section 3.2);
- procedures for labelling of each reconstituted medicinal product, if it leaves the hands of the person who has reconstituted it, to ensure that the prescription, the product (active pharmaceutical substance, dosage; time of administration of the reconstituted medicinal product) and the patient’s identity (given and family names) information match and the reconstitution procedure is traceable (identity of the person who has reconstituted it);
- a system for documenting individual reconstitutions, including calculations performed, as applicable;
- a list of medicinal products (generic name and trade name, where applicable, strength, container, dosage), which can be reconstituted in the clinical area under these minimum requirements;
- documented evidence of the competency of personnel to reconstitute medicinal products (qualification document for each person involved in reconstitution, approved by the management of the specific clinical area).

If the above-mentioned requirements are not met in a specific clinical area, reconstitution should not take place there (see item 3.2).

As a general rule, the reconstitution of medicines that are hazardous or pose a safety risk, e.g. cytotoxics, certain biologicals (in particular, monoclonal antibodies) or medicinal products which require special attention at the time of reconstitution (filtration of solutions containing micelles, products with slow dissolution, certain monoclonal antibodies that are fragile, etc.), should take place in an environmentally controlled area in the pharmacy or under the full responsibility of a pharmacist. This may also apply to other products e.g. certain biologicals and gene therapy products depending on the level of risk they pose to operators.

Medicinal products should be reconstituted in clinical areas ideally as close as possible to the time of administration or use.

Reconstituted products should be handled and stored in accordance with SmPC, if otherwise, only if justified and outside the manufacturer’s responsibility. Medicinal products reconstituted in clinical areas should be stored as required in the SmPC. Otherwise, storage limits should be only indicated if stability studies are available.

## 5. Handling the risk of reconstitution in clinical areas

To minimise the risks for patients posed by medical products reconstituted in clinical areas, the following activities should be undertaken in line with risk management principles:

- risk identification;
- risk assessment;
- risk management;
- risk acceptance;
- risk review.

### 5.1 *Risk identification*

The following situations should be considered as complex and therefore, as bearing risks: Risks associated with complex reconstitution procedures are listed below and considered in the Checklist (see Note). This is not an exhaustive list and each reconstitution should be assessed individually.

#### 5.1.1. *Product related risks and those related to reconstitution procedures*

##### 5.1.1.1 *Microbiological contamination*

- Complex method of reconstitution: the more complex the method of reconstitution, the more the medicinal product is susceptible to microbiological growth.
- Open-system procedure: if the medicinal product is not administered immediately after reconstitution in clinical areas, as it ideally should be, the risk of microbiological contamination is increased.

##### 5.1.1.2 *Incorrect composition*

- Use of a concentrate: where further dilution (after reconstitution) is required before use such as with concentrated electrolytes, there is a greater risk of incorrect composition.
  - Complex calculation: the more complex the calculation, the greater the risk of incorrect composition;
  - any calculation with more than one step for preparation;
  - any calculation with more than one step to prepare for administration;
  - dose unit conversion required;
  - complex fractions or decimal places involved;
  - the need to consider a displacement value;
  - the medicinal product is a powder that requires dissolution as part of the reconstitution.
  - where a dry powder has to be reconstituted with a diluent there is a risk that the powder does not dissolve completely before the product is administered which can lead to incorrect composition and the risk of particulate contamination.

Dividing the contents of a vial or multiple vials: where the use of a part vial or ampoule, or use of more than one vial or ampoule is required, the risk of incorrect composition increases as measurements of volumes are required.

#### 5.1.2 *Risks for the staff performing reconstitution (see section 4)*

#### 5.1.3. *Risks related to the pharmacological activity*

Certain medicinal products for parenteral administration pose a significant risk of health damage to the patient if not used as intended. The risk to the patient depends upon the pharmacological activity of the medicinal product.

### 5.2. *Risk assessment*

Use could be made of the Checklist (see Note) to identify which risks are relevant. This procedure will enable the ranking of products into those that are higher risk (where reconstitution in clinical areas should be avoided unless risk reduction measures are introduced – see below). Lower risk products may be able to be safely prepared in clinical areas, although the minimum requirements stated in section 4 should be in place.

Certain risks are sufficiently great to dictate that the product cannot be reconstituted in the clinical area and must be provided in RTA form e.g. cytotoxic medicinal products.

Alternative risk assessment methods are allowed as long as they apply the same rigorous criteria.

Similar medicinal products may be assessed group-wise to reduce the workload. This will depend on the medicinal product and also on the situation in the specific clinical area.

### 5.3. *Risk management*

Irrespective of the results of the risk assessment, the aim should be to reduce risks associated with the reconstitution procedure in all cases. Suggested risk reduction methods that should be considered to minimise risks with reconstitution of parenteral medicines are:

- provide RTA or RTU parenteral products – this will minimise reconstitution risks of all types and simplify administration. These products may be able to be either prepared in pharmacy or sourced in this form. This is the ideal risk management solution;
- simplify and rationalise the range of products and presentations of parenteral medicines. Where possible, reduce the range of concentrations/strengths of higher risk products to reduce the risk of selection error;
- provide the most appropriate vial/ampoule sizes at the most appropriate concentration. The risks of microbiological contamination are less with vials than with ampoules as the product is in a closed system. Vials should be used in preference to ampoules if they are available to reduce the risk of microbiological contamination. Using the most appropriate sized container and correct concentration will reduce the need for partial withdrawals that require measurement of volume. Hence this will reduce the complexity of the procedure and the risk of incorrect composition;
- if reconstitution occurs as open system, consider if it is possible to use a device that will make the reconstitution into a closed system;
- use double-checking systems – an independent second check from another person and/or the use of dose-checking software in 'Smart' infusion pumps and syringe drivers will reduce the risk of calculation error and incorrect composition;
- provide dose calculating tools – for example, dosage charts for a range of body weights that eliminate the need for dose calculations. This will reduce the risk of calculation error and incorrect composition;
- provide additional guidance on how to prescribe, reconstitute and administer those products that have been assessed as higher risk parenteral medicines. This will reduce risks of all types;
- provide protective equipment in the clinical area. This will reduce risk of microbiological contamination in the product and, in certain cases, risks to the staff performing reconstitution. As a minimum, a separate space for reconstitution is recommended in clinical areas;
- consider the provision of pre-printed prescriptions or stickers – this will help to ensure that the information on the prescription about the reconstitution and administration of medicinal products carrying a higher risk is clear;
- provide locally approved protocols that clarify approved unlicensed and 'off-label' use of parenteral medicines;
- use of an infusion monitoring form or checklist – this will help to ensure that infusions are monitored throughout administration and reduce risks to patients. If possible, include the form or check-list in the patient file in the case of intravenous infusions that carry a higher risk, or in clinical areas which do not frequently carry out reconstitution;
- encourage an open and friendly environment among the professionals involved, where a lack of confidence is accepted as a reason to seek help and obtain support.

All of the above risk reduction methods should be considered for each of the specific reconstitution steps and those that are applicable and practical should be implemented in each case.

### 5.4. *Risk acceptance*

After all risks have been identified for a specific reconstitution procedure, and all risk reductions (see E in the checklist below) have been considered and implemented where possible in each case, there remains a 'residual risk' of the reconstitution. Medicinal products to be reconstituted should be ranked according to

their residual risk with the chosen risk reduction methods in place. Those with the higher residual risk should not be reconstituted in clinical areas and alternatives should be sought e.g. provision of a RTA product or by preparation in pharmacy (see section 3.2).

### 5.5. Risk review

All remaining risks should be reviewed regularly (suggested at least annually) to update the health care establishment's data on the most appropriate location for the specific reconstitution to take place. Additional risk reduction methods may have become possible since the previous risk review. For example, the pharmaceutical industry may have authorised a RTA form. Alternatively, the health care establishment may have become aware of risk reduction measures in place in other establishments that could also be implemented in their own.

**Note:** Checklist for the identification, assessment and reduction of risk posed by the reconstitution of medicinal products in clinical areas

Product:	Clinical area:	Assessment completed by:	Date:
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I. Risks		Assessment
<b>Product related risks</b>		
<b>A Microbiological contamination</b>		
A1	Is the reconstitution <b>complex</b> ? - More than five aseptic non-touch manipulations involved in the procedure; - Reconstitution includes a complex technique such as: syringe-to-syringe transfer, filtering.	Yes <input type="checkbox"/> No <input type="checkbox"/>
A2	Is the product <b>susceptible to microbial growth</b> ? e.g. propofol	Yes <input type="checkbox"/> No <input type="checkbox"/>
A3	Does reconstitution involve an <b>open-system</b> procedure?	Yes <input type="checkbox"/> No <input type="checkbox"/>
A4	Is the medicinal product to be stored i.e. not used immediately?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>B Incorrect composition</b>		
B1	Does reconstitution involve use of a <b>concentrated medicinal product</b> ? e.g. slow bolus injection is not advised.	Yes <input type="checkbox"/> No <input type="checkbox"/>
B2	Does reconstitution involve a <b>complex calculation</b> ? - Any calculation with more than one step for preparation (e.g. double or series dilution); - Any calculation with more than one step to prepare for administration (e.g. mg/kg/hour (excludes weight based calculations where the calculation is part of the prescribing stage); - Dose unit conversion required (e.g. mg to mmol or % to mg); - Complex fractions or decimal places involved mg/hour or mg/day delivery for syringe drivers e.g. in palliative care; - The need to consider a displacement value.	Yes <input type="checkbox"/> No <input type="checkbox"/>
B3	Is the dosage form of the medicinal product to be reconstituted a <b>powder, lyophilisate, suspension or emulsion</b> ?	Yes <input type="checkbox"/> No <input type="checkbox"/>
B4	Does reconstitution involve use of a <b>part vial or ampoule</b> , or use of more than one vial or ampoule? e.g.: 5ml required from a 10ml vial or four times 5ml ampoules required for a single dose.	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>C Risks for the staff</b>		
C1	Is the product <b>cytotoxic</b> ? e.g. overall procedure for reconstitution that covers general aspects such as aseptic handling, hygiene, any special clothing requirements; policy on independent checking, requirement to use immediately; - documented evidence of the competency of personnel to reconstitute medicinal products (qualification document for each person involved in reconstitution, approved by the management of the specific clinical area).	Yes <input type="checkbox"/> No <input type="checkbox"/>
C2	Is the product <b>hazardous in any other way</b> ? e.g. biologicals.	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>D Risks related to the pharmacological activity of the medicinal product</b>		
D1	Does the medicinal product carry a specific therapeutic or pharmacological risk?	Yes <input type="checkbox"/> No <input type="checkbox"/>



	<i>e.g. insulin, opiates.</i>	
<b>E</b>	<b>Any other risks not recorded above</b>	
E1	Reconstitution procedure longer than usual.	Yes <input type="checkbox"/> No <input type="checkbox"/>
E2	Unstable active pharmaceutical substance requiring special precautions during reconstitution or handling of the medicinal product ( <i>e.g. monoclonal antibodies</i> ).	Yes <input type="checkbox"/> No <input type="checkbox"/>
E3		Yes <input type="checkbox"/> No <input type="checkbox"/>
	<b>II. Risk reduction methods currently in place</b>	
<b>a</b>	RTA or RTU product available in clinical area?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>b</b>	Simplest range of concentrations/strengths/forms of parenterally administered medicinal products in use?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>c</b>	Most appropriate vial/ampoule size and concentration in use?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>d</b>	Using a device to convert an open system into a closed system?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>e</b>	Independent second check from another person and/or the use of dose-checking software in place?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>f</b>	Dose calculating tools available? e.g. dosage charts for a range of body weight	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>g</b>	Additional guidance available on higher risk parenteral medicines?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>h</b>	Protective equipment available? e.g. an isolator	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>i</b>	Pre-printed format of labels available?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>j</b>	Locally approved protocols available for off-label or unlicensed use of the product?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>k</b>	Infusion monitoring form or checklist in use?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>l</b>	All requirements of handbook fulfilled (SmPC, leaflet)?	YES <input type="checkbox"/> No <input type="checkbox"/>
III. Product suitable for reconstitution in clinical area:		YES / NO
Justification of the decision:		

#### Use of the Risk assessment checklist

- All risks associated with the reconstitution of a particular medicinal product (or group of similar products) in a particular clinical area should be identified by ticking "yes" if they apply.
- On the basis of the risks identified and the risk reduction methods in place, i.e. the residual risk, the manager of the clinical area involved and the designated person should agree whether or not the product is suitable for reconstitution in that specific clinical area, and the reason for this decision. This should be recorded on the checklist (see section 5.4. Risk Acceptance section).
- A pharmacist should complete steps I-III and should sign "assessment completed by" and insert the date into the fields at the top of the checklist.
- The checklist should be signed by both the manager of the clinical area and the designated person overseeing the assessment.
- A date when the risk assessment should be reviewed (suggested at least annually) should be added to the completed checklist (see section 5.2 Risk Review section).
- The completed risk assessment checklist should be kept on file in the clinical area.
- Superseded completed risk assessment checklists should be clearly marked as such but retained for audit purposes.