SECOND SURVEY
TEXT ACCOMPANYING THE FLOW CHART
FOR THE PHARMACEUTICAL ANALYSIS
OF RADIOPHARMACEUTICAL PEDIATRIC PRESCRIPTION

The dispensation of medication is defined in the Code de la Santé Publique (French Public Health Code) as the pharmaceutical acts associated to the delivery of medicine: pharmaceutical analysis of the medical prescription, supply of information and advices for correct usage of medication and preparation of doses to be administered.

This flow chart is applicable to radiopharmaceuticals (medication and implantable radioactive medical devices) prescribed for an exam or a treatment for patients under 18 years old. This flow chart do not concern medication under regulation prescribed, for clinical trials or delivered outside the hospital (thyroid blockers, anxiolytic drugs ...)

The following items included in the preliminary requests for pharmaceutical analysis of pediatric radiopharmaceutical prescription:

- Fixed appointment (date, hours of the exam or treatment);
- For computerized prescription, parameters in relation to training (prescription for nuclear medicine physicians and pharmaceutical validation for radiopharmacists);
- Availability of the medication ;
- Availability of the medical devices necessary for the preparation;
- Testing of the equipment (flow hood) ;
- Validation of documents (procedures, patient advice leaflet) containing advices to patient (fasting, pregnancy ...);
- If possible, putting in place of the specific circuit for pediatric patient.

The pharmaceutical analysis is realized in three steps of verification:

- Presence of regulatory data (computerization could secure this step);
- Patient data (check must be adapted to each radiopharmaceutical);
- Medication data.

During these verifications, additional information may be required from the prescriber. The pharmacist gives advice during the pharmaceutical analysis. This advice must be traceable. The article R 4235-61 of the Code de la Santé Publique stables that the pharmacist should refuse to deliver medication if necessary, in the interest of the health of the patient. The pharmacist should immediately inform the prescriber of his refusal and it must traceable.

Information is collected during pharmaceutical analysis and transmitted to the person in charge of the preparation and/or preparation of doses to be administered:

- Choice of medical devices (example: luer lock syringe for central Intravenous injection...);
- Specific procedures for preparation (example: respect of the number for aggregated human albumin...)

SECOND SURVEY
FLOW CHART FOR RADIOPHARMACEUTICAL PRESCRIPTION ANALYSIS IN PEDIATRICS

Medical prescription of the radiopharmaceuticals

- date of prescription
- identification of prescribing physician (name and qualifications)
- signature
- authorization of prescribing physician
- name of hospital and nuclear service department
- patient identification: name, surname, sex, age (birth date), weight, height, (+/- identification number)
- prescription in International Nonproprietary Names
- for blood-derived medicine: specific traceability

Check legal requirements:

Regulatory compliance

Patient data:

- weight check
  - patient’s medical record available, check:
    - pathology
    - medication history
    - current prescriptions (not included medication)
    - allergy
    - intolerance
    - respect for optimum interval between chemotherapy/raditherapy/growth factor
    - imagistry history (other radiopharmaceutical prescriptions)
  - necessary and if biological data available, check:
    - renal function (creatinine)
    - hepatic function
    - platelet count

All items are OK

Radiopharmaceutical data, check:
- prescription compliance with request form
- indication mentioned in marketing authorization
- compliance with institutional protocols
- posology: minimum recommended dose for adequate imaging; iobenguane 131I posology is determined after pre therapeutic administration of iobenguane 131I, dosage cards EANM
- contraindications: age (premature infants, newborn children, benzyl alcohol presence, pregnancy...)
- drug interactions
- route and mode of administration, specify injection site (left/right for Sentinel lymph node scintigraphy

All items are OK

Pharmaceutical validation
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pharmaceutical opinion drafting (traceability)