

The future Radiopharmacy: challenge and/or opportunity?

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“the future of nuclear medicine lies in the development of new radiopharmaceuticals”



^{177}Lu -PSMA

^{177}Lu -SSA

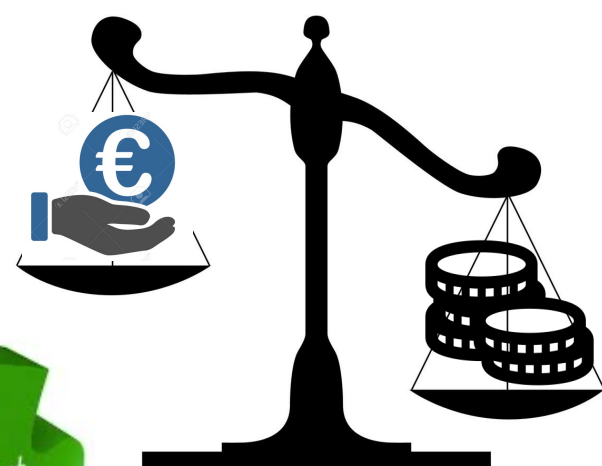
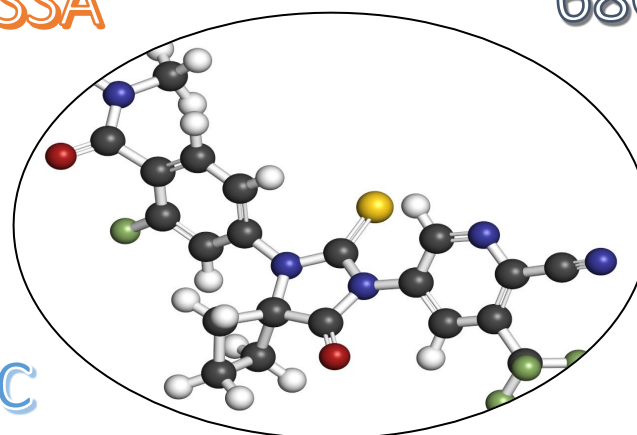
$^{68}\text{Ga}/^{18}\text{F}$ -PSMA

$^{68}\text{Ga}/^{18}\text{F}$ -SSA

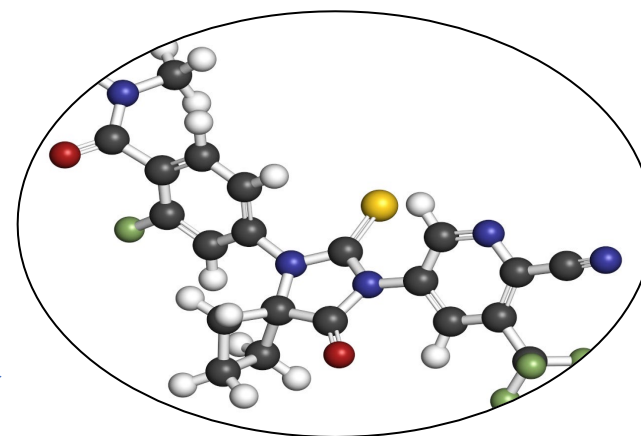
^{18}F -FAPI

$^{223}\text{RaCl}_2$

^{225}Ac



Challenges for Introducing a new radiopharmaceutical



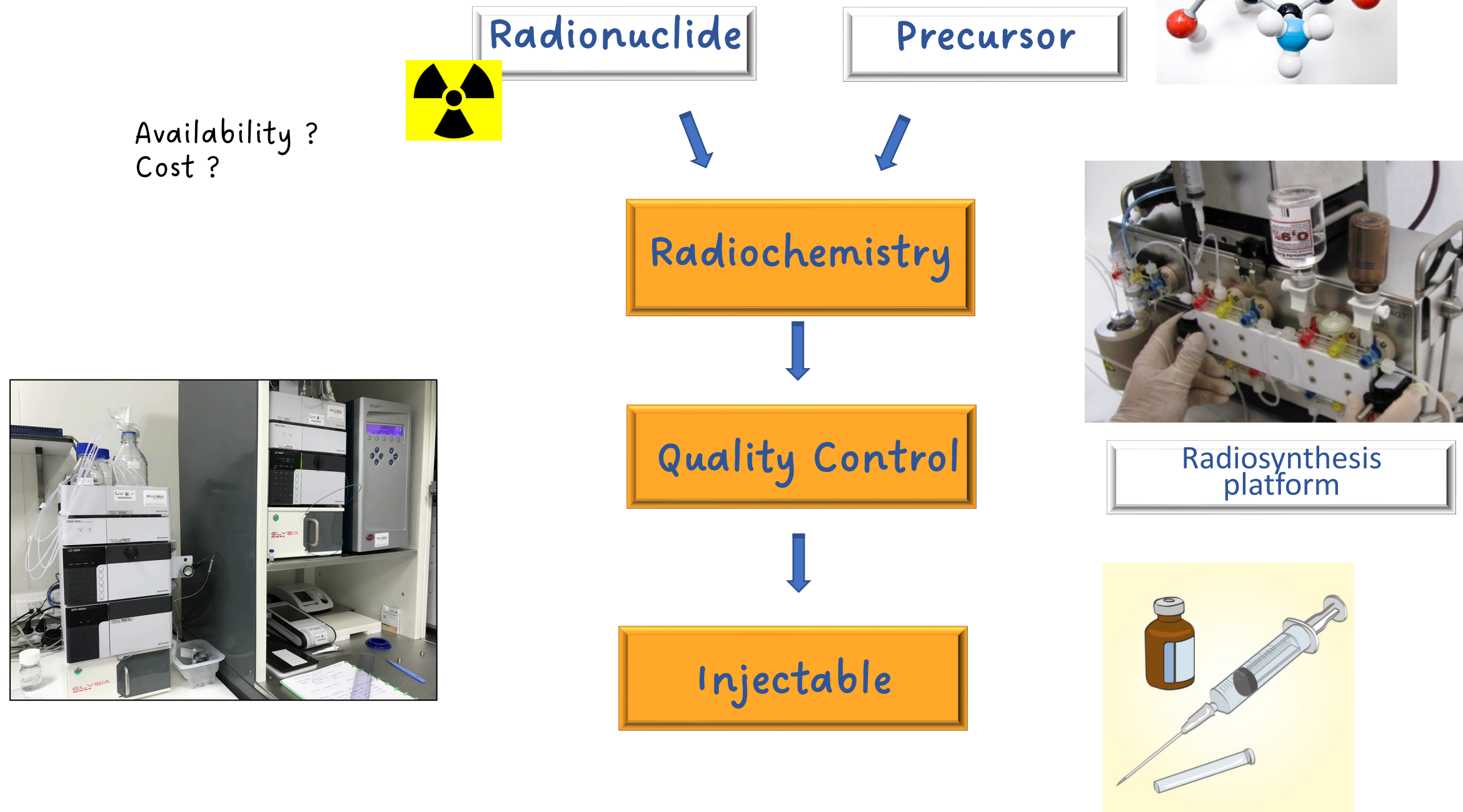
Commercial product?



In-house preparation?



In-house radiosynthesis



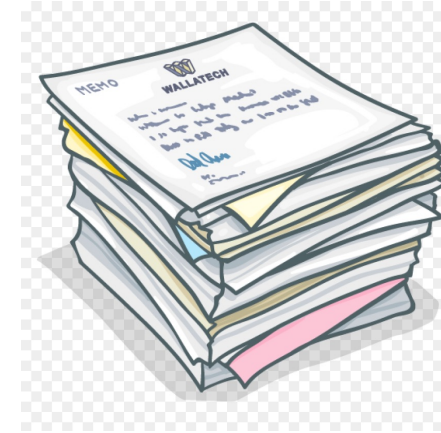
18F-PSMA-1007 ?
18F-PSMA-JK-7 ?
18F-DCFPyL ?

Availability ?
Cost ?
Licenced?

Plug and play ?
Development?



In-house radiosynthesis :



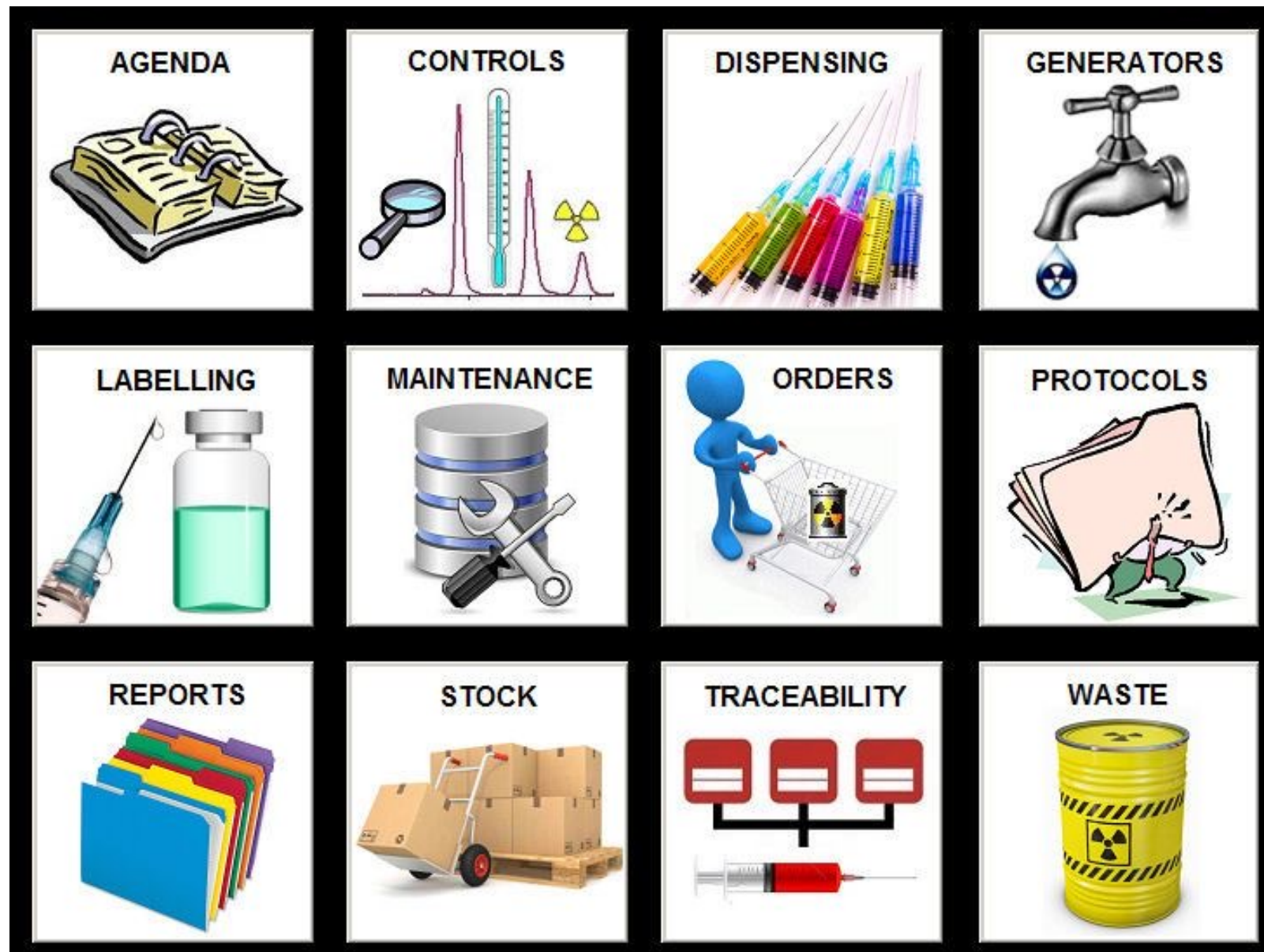
- FANC authorization needed per product

 FANC FEDERAAL AGENTSCHAP VOOR NUCLEAIRE CONTROLE	 AFCN AGENCE FÉDÉRALE DE CONTRÔLE NUCLÉAIRE
Departement Gezondheid en leefmilieu Dienst Bescherming van de gezondheid	
AANVRAAGFORMULIER ¹ VOOR OPNAME VAN EEN RADIOACTIEF PRODUCT IN EEN VERGUNNING ² VOOR HET TER BESCHIKKING STELLEN VAN RADIOACTIEVE PRODUCTEN VOOR <i>IN VIVO</i> OF <i>IN VITRO</i> GEBRUIK IN DE (DIER)GENEESKUNDE	

- Reimbursement application
CTRI-TRRI



In-house radiosynthesis : GRPP



Challenges:

- Dedicated equipment needed (cyclotron/generator, hotcells, synthesis modules, QC equipment, ..)
- Specialized staff (radiopharmacist, trained operators)
- Small scale, high cost
- Time-consuming

Opportunities:

- Wider range of products
- Flexibility



Regulatory challenges

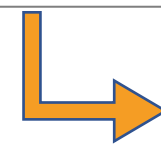
- Belnuc meeting 19th november 2022



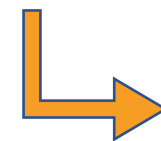
- Implementation of PIC/S guide to good practices for the preparation of medicinal products in healthcare establishments **1/1/2026**



KB 30 September 2020: art.21§2: “De apotheekbereidingen moeten gebeuren overeenkomstig de PIC/S-normen, zoals opgenomen in Bijlage III./ Les préparations de la pharmacie doivent être effectuées conformément aux normes PIC/S, tels que repris dans l’Annexe III”
PIC’s guideline include Annex 3: Good practices for the preparation of radiopharmaceuticals in healthcare establishments.



Organisation : quality system, staff



Infrastructure : e.g. classified area, depending on type of rph preparation

- ^{99m}Tc-radiopharmaceuticals and/or ready-to-use ? What is required?



Regulatory : how do we proceed?

- Belnuc meeting 19/11/2022: no clear position from FAMPH but open for dialogue
- Initiative from the Belnuc:
BELNUC/BARR working group on radiopharmacy legislation
nuclear med physicians (academic/peripheral hospitals) + (radio)pharmacists
- BARR: proposal text to start further discussion regarding PIC/S implementation/interpretation from the radiopharmacy standpoint
- FAMPH was contacted in Febr for a 1st meeting, reminder in March –
answer received last week:

“.. we are fully aware that a dialogue is essential on this subject.. We therefore suggest to answer to all the questions you can have now or in the future.. We propose to host a meeting with BARR and BELNUC in a near future to discuss on these topics. “

To be continued..



Centralized radiopharmacy or collaborations

- Current situation in Belgium for ^{99m}Tc -radiopharmaceuticals:
each nuclear medicine department is procuring generators and kits
radiolabelling is performed by (trained) technicians/nurses under the supervision and responsibility of a physician (hospital pharmacist?)
- Current situation in US and other European countries for kit radiopharmaceuticals:
Centralized radiopharmacies : radiopharmaceutical product is distributed to the adjacent nuclear medicine departments on demand,
as prescribed unit doses or in multi-doses for dispensing
- Art.23. KB/AR Hospital Pharmacies 4/03/1991 and 30/09/2020 :
makes collaborations between hospital pharmacies possible



Centralized radiopharmacy



Local

most nuclear medicine departments
near patient
respond to acute clinical demand
flexibility
reasonable costs

challenge or opportunity?



infrastructure ? room for improvement
few personnel, (radio)pharmacist ?
QC/QA ?
Operational costs will increase



Centralized

high-level infrastructure & equipment
specialized and dedicated staff
ready-to-use dispensing -> ready-to-use
access to a wide range of products
no investments in laboratories and
personnel for clinical dept
higher quality

less flexibility to respond to acute
clinical demand
logistics
legal
cost?



Take home messages..

- Many challenges, but also many opportunities
- Work together
 - .. with the hospital pharmacy
 - .. with hospitals in your network
- BELNUC/BARR will follow-up on regulatory aspects



THANKS
FOR
LISTENING

