Shall the regulator link the justification of new types of practices to the authorisation process?

Case Study : Luxembourg

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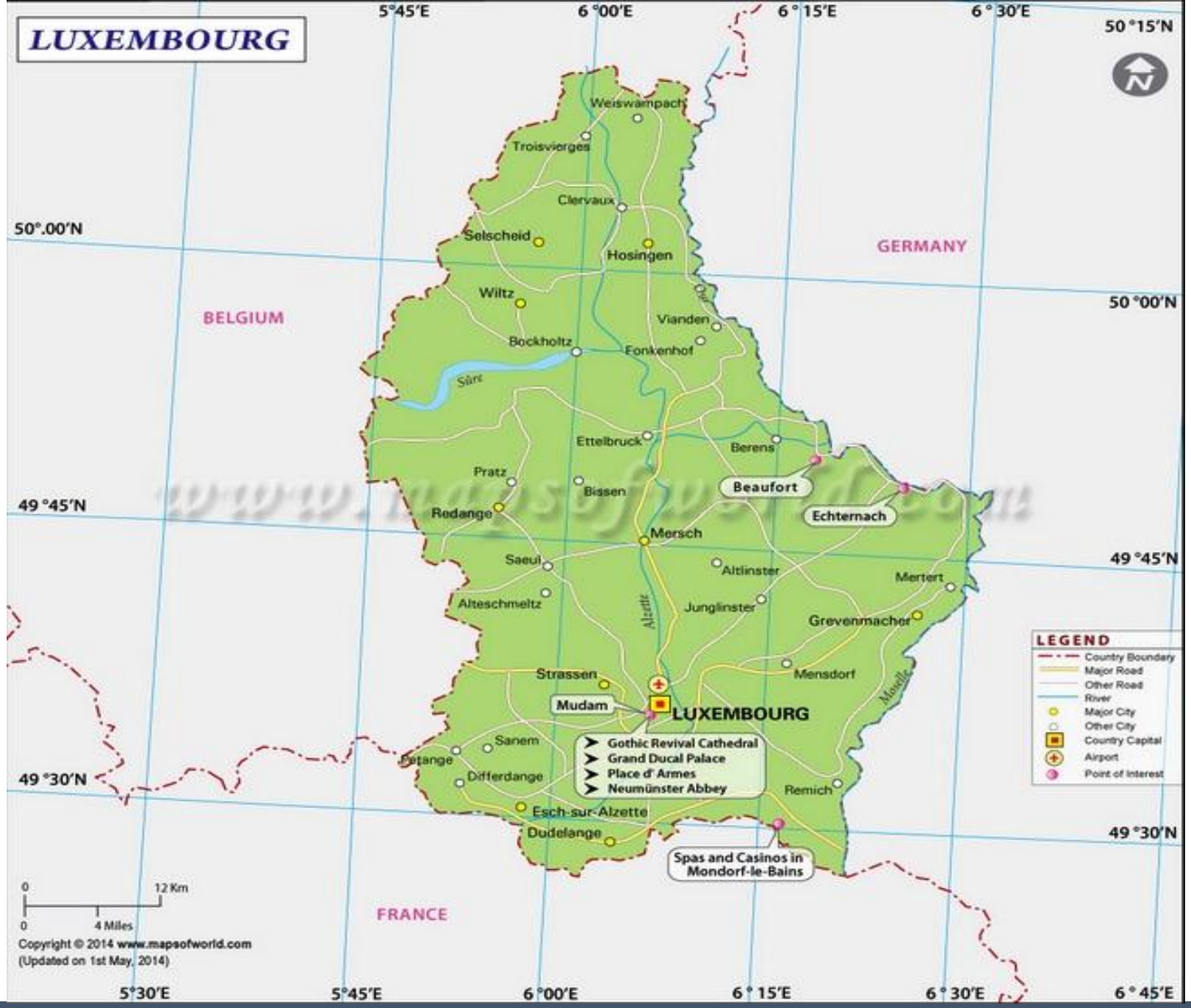
Some facts about Luxembourg

- Small country
- Population ≈ 600.000
- Public health care system
- 4 private practices mainly pulmonologists
- ≈ 400 dentists


LUXEMBOURG
5°45'E
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6°30'E
50°15'N
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49°30'N
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GERMANY
BELGIUM
FRANCE
Weiswampach
Troisvierges
Clervaux
Selscheid
Hosingen
Wiltz
Vianden
Bockholtz
Fonkenhof
Sûre
Ettelbruck
Berens
Pratz
Bissen
Beaufort
Redange
Echternach
Mersch
Saeul
Altlinster
Mertert
Alteschmeltz
Junglinster
Grevenmacher
Alzette
Strassen
Mensdorf
Mudam
LUXEMBOURG
Moselle
Sanem
Petange
Differdange
Gothic Revival Cathedral
Grand Ducal Palace
Place d' Armes
Neumünster Abbey
Remich
Esch-sur-Alzette
Dudelange
Spas and Casinos in Mondorf-le-Bains
LEGEND
Country Boundary
Major Road
Other Road
River
Major City
Other City
Country Capital
Airport
Point of Interest
0
12 Km
0
4 Miles
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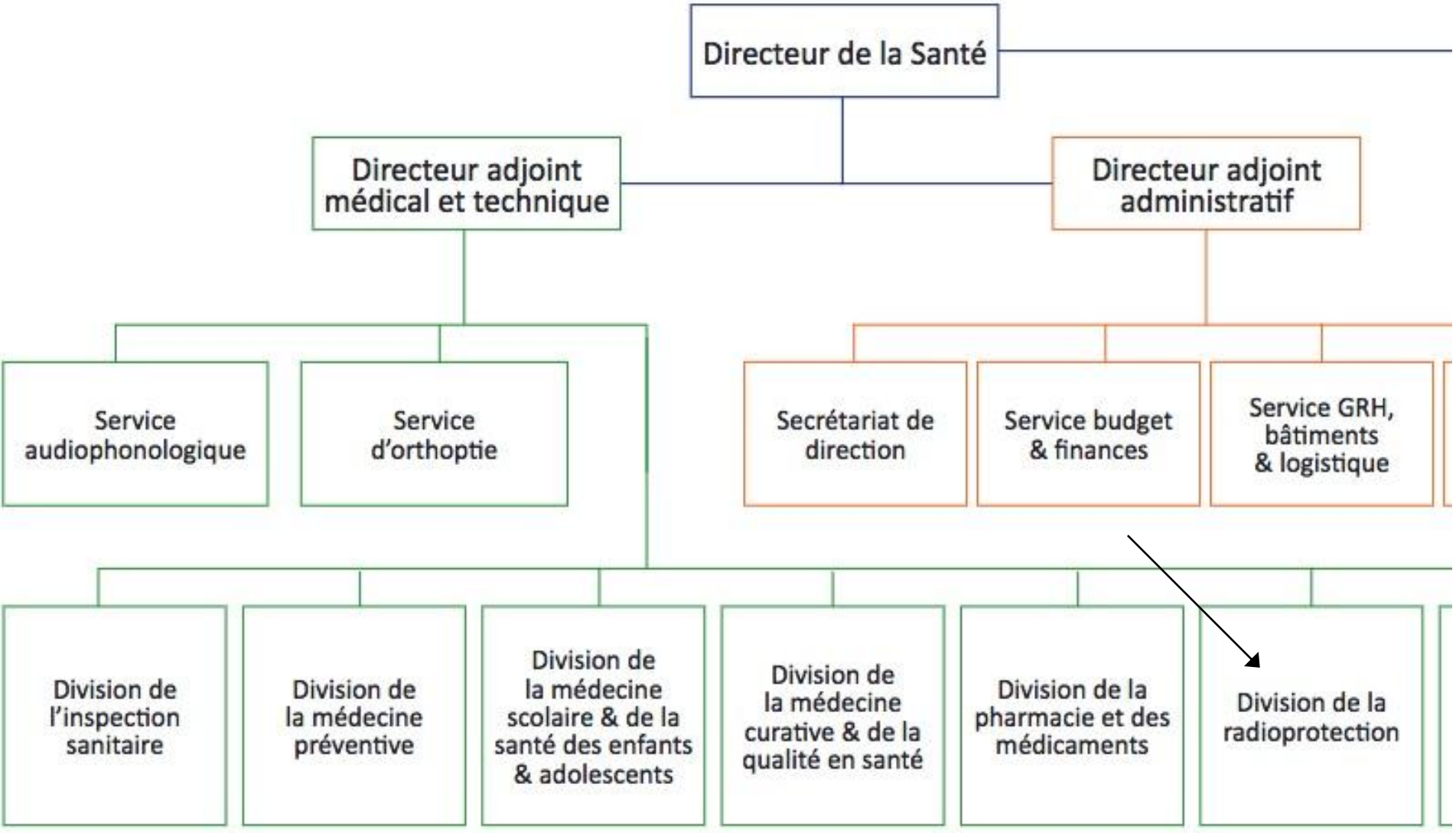
Hospitals

- 10 Hospitals
- 10 Radiology Dpts
- 4 Nuclear Medicine Dpts
- 1 Radiotherapy Dpt.
- ≈ 160 radiology installations

Ministry of Health: Competent Authority



Authorisation Process

- An authorisation is given for the installation and use of each and every radiological installation and radio-isotope
- The authorisation is given by the Ministry of Health
- The demand for the installation of radiological equipment or use of a radio-isotope is addressed to the Ministry of Health ➔ Directorate of Health➔ Radiation Protection Division
- For radio-isotopes➔ Ministry of the Environment

Authorisation process for new practices

- The undertaking has to submit a demand for the new practice which will allow for the establishment of the Justification of the new practice
- In the case where new information comes to light concerning the efficacity, the potential consequences of the new practice or information on other technologies the DRP can ask the undertaking to update its justification
- Specific regulations detail the information/documents to be submitted in a file to the Ministry of Health

Authorisation process for new practice

- The file is submitted to national and / or international experts for advice

- If the beneficial or detrimental effects of a new practice are not yet completely known the authorisation can be given for a defined period of time and under certain specified conditions

Information to be provided by the undertaking

- Description of the new practice
- Referral guidelines
- Radiation protection measures and security
- Written procedures
- Quality assurance program
- Quantification of the no of acts to be done

Information to be provided by the undertaking

- Quantification of the advantages for the patient and the society
- Estimation of the risk for the professionals exposed, the patient and the patients entourage
- Names and signatures of the persons responsible for putting into practice the new practice: Practitioner, Physicist, Radiographer ….
- Proposal of a methodology for the evaluation of the benefits for the patients after 1 year

Authorisation process for a new practice

- If the new practice already exists in another EU country documents recognising this practice for the EU country can be submitted
- In the authorisation of this new practice conditions will be set concerning for example:

✓ Education and training

✓ QA

✓ Referral guidelines

✓ other

Authorisation process for a new practice

- It can also ask for the re-evaluation of the new practice after 1 year concerning:

✓ risk-benefit

✓ Constraints for the personnel

✓ no of patients

✓ other

Article 78 of the BSS

- The Manufacturer provides the undertaking with all the necessary information concerning:

✓ radiation protection risks

✓ Correct use of equipment

✓ maintenance

✓ QA

✓ Adequate information on the risk evaluation for the patient and on the clinical evaluation

Authorisation process for a new practice

- The DRP can contact the Manufacturer for supplementary information where necessary
- Members of the DRP are also members of a no of scientific and radiation protection committees for radiotherapy, PET_CT, Cardiology etc
- Excellent collaboration with the heads of the radiology, radiotherapy and nuclear medicine Dpts.

Examples

Ra ^{223}

- authorisation given initially for 1 year and for 5 patients per hospital due to potential waste management problems
- After 1 year a report was written by the doctors evaluating the use of the Ra ^{223}
- 1 hospital decided it was not justified to continue with this treatment and decided to stop
- The DRP evaluated the waste problem and found it not to be a problem
- Authorisation was given for indefinite time and no of patients

Potential Pitfalls

- System works well for new types of equipment or radio-isotopes
- Difficulties arise for the use of existing equipment and radio-isotopes for new practices
- Need to not only authorise the equipment or radio-isotope but also the practices for which the equipment or radio-isotope will be used

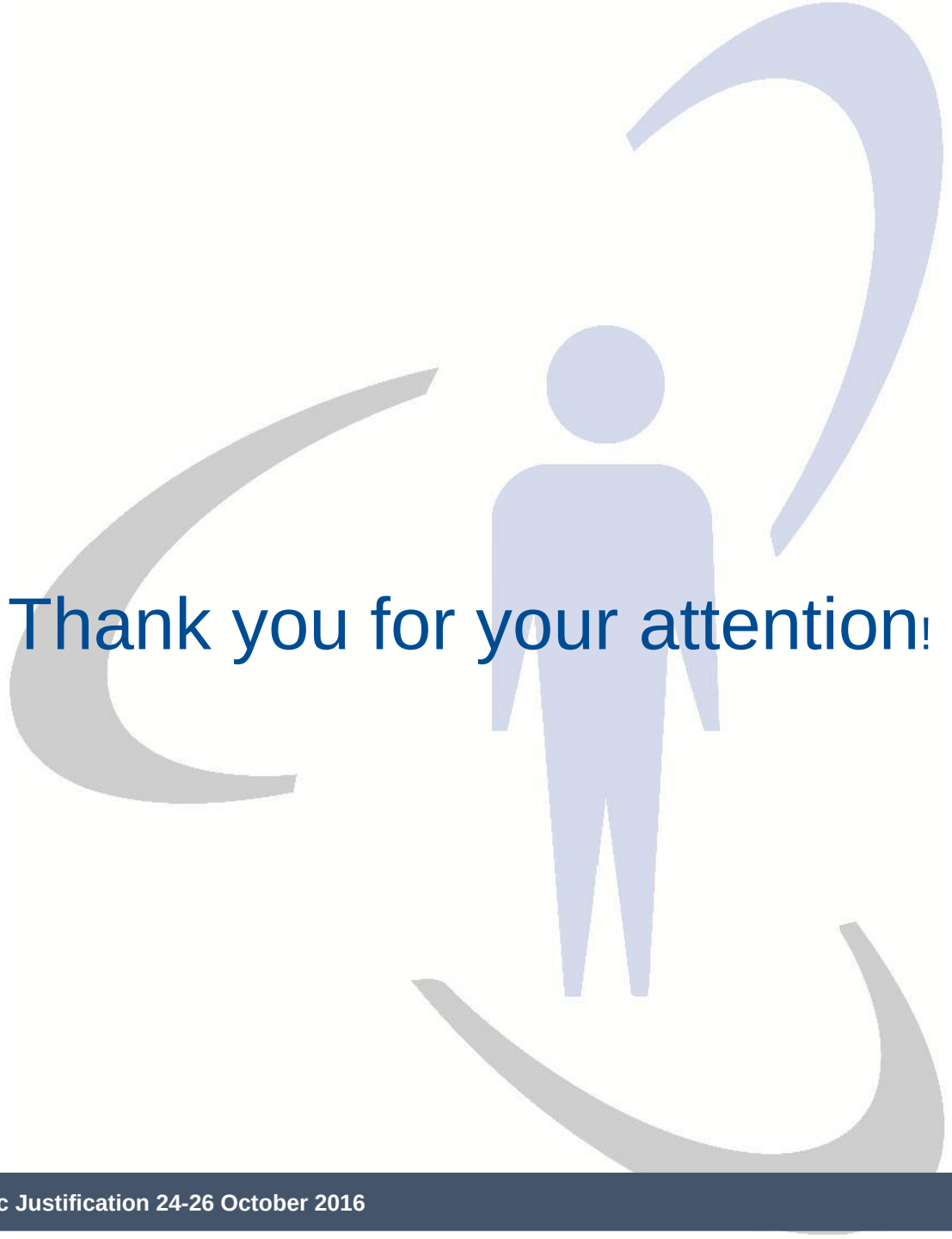
Example

^{90}Y

- Authorisation given for a defined amount of ^{90}Y per year
- Justification: use of ^{90}Y for the treatment of inflamed joints
- Hospital decides to use ^{90}Y for radioembolisation
- This is a new type of practice with important radiation protection issues however hospital ignores this
- Hospital was informed by the DRP and procedures were put into place according to new practices

Conclusions

- The system works well
- All stakeholders are made responsible for the new practice
- Authorisation is given with strict conditions which have to be respected
- A lot of work for the competent authority



Thank you for your attention!