HERCA
HEADS OF THE EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES

Working Group
Medical Applications

Case Study: Czech Republic

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Czech situation with EU BSS

- Some requirements were transposed in 2011 - 2012
  - Mostly the „clinical“ articles from the medical exposures (justification, optimization, responsibilities) and education and training of health professionals
  - Most of these requirements were in a draft of EU BSS in 2011 and remained unchanged
  - And that time a new health law was created in The Czech Republic
  - So we put these requirements in this legislation from the EU BSS draft
  - So I will speak about the requirements of the health law which are in the responsibility of Ministry of Health (not the RP competent authority)
- The rest will be transposed on 1st January 2017
  - We have already finished the new Atomic Act
  - and the new Regulation on Radiation protection is currently being finished

Generic Justification in CZ health law

Question in discussion paper (last in section VI.):

What further approaches exist in MS for the transposition of Art. 55.2 (a) Council Directive 2013/59/Euratom and other articles around it?

The CZ approach follows

- Radiological procedures (diagnostically or therapeutically) are medical procedures
  - Ionizing radiation is only one of many risks related to the health care
  - In CZ the generic justification is a fully covered by normal HTA process

Generic Justification in CZ health law

- Law n. 373/2011 of the Specific Health Services – Section 33
  - Verification of the non-established methods (i.e. medical or biomedical research) can be done on an alive human being only under following conditions:
    - Patient informed and agrees,
    - expectation of benefit to the tested patient and of creating new way of prevention, diagnosis or treatment,
    - the verification can‘t be done any other way,
    - no danger of harming of the tested patient
    - Special conditions for children, patients without legal capacity and prisoners
  - Non-established method aren‘t
    - methods established in some EU Member state, in a state of the European Economic Area or in the Switzerland
    - Or modification of an established method that haven‘t adverse effect on a health of the patient
- ***This transposes EU BSS art. 55.2 (a)***

sect. VII. Q 1: **When a type of practice is not – yet – justified in general according to Art. 55.2 (a), is it then to be handled under the provisions of bio-medical research according to Art. 55.2 (e)?**

Yes

Generic Justification in CZ health law

- Law n. 373/2011 of the Specific Health Services – Section 35
  - Ministry of Health must authorize the verification.
  - The request for this authorization comes from the undertaking and must contain:
    - Description and reasoning (justification) of the method,
    - Report of laboratory testing and actual knowledge related to the method
    - Detailed plan of the verification, workplace where it will be done with names of professionals who will do and manage it (with their qualification)
    - Assessment of health risks considering all the available information
    - Information about characteristics of a group of the tested patients
    - Binding opinion of State office for Nuclear Safety (RP Competent authority) when it contains medical exposure

sect. IV. Q 1: **By what action shall the regulatory process be initiated, in particular for new types of practices:**

re-actively by e.g. undertakings, but not within a notification / authorization process but within the HTA process

Generic Justification in CZ health law

- Law n. 373/2011 of the Specific Health Services – Sections 37, 38
  - The undertaking who will be verifying must establish an ethical comity
    - It must be independent
    - It must judge from ethical point of view the verifying
    - It must supervise the verification – the safety and laws of the patients
    - At least 5 members. None of them must have a personal interest on the verifying
    - Members are health professionals and other persons and at least 2 thirds mustn‘t have relationship with the undertaking
    - If they find some fact that indicates non-complying of the conditions of verifying, they must immediately inform the undertaking and the Ministry
- ***This transposes EU BSS art. 55.2 (e)***

Generic Justification in CZ health law

- Law n. 373/2011 About the Specific Health Services – Section 39
  - The undertaking must
    - Report about the verifying to the Ministry regularly
    - Immediately stop the verifying if there is some questioning about the reasoning (justification) of the verified method or if it could harm the patient, and must immediately inform the Ministry about it
    - Immediately inform the Ministry (and in case of medical exposures also the RP competent authority) about an adverse event
    - Enable a control of the Ministry, (the RP competent authority) or ethical comity
    - Send a final report to the Ministry (and the RP Competent authority)

Generic Justification in CZ health law

- Law n. 373/2011 About the Specific Health Services – Section 40
  - The Ministry
    - Than evaluates the verification
    - Than issues a decision that accepts the method as established, or doesn‘t accept it.
    - Than publishes the accepted established method or unaccepted method in its bulletin

sect. IV. Q 3: **What shall the outcome of the regulatory process be**

re-active approach: approval with respect to ***HTA*** processes

sect. VIII. Q 2: **How to progress from the status of research according to Art. 55.2 (e) to the status of generally accepted type of practice according to Art. 55.2 (a)?**

By official ending of the research, reporting to the Ministry about it and that the Ministry than accepts the method as established

Generic Justification in CZ practice

- Methods established in other European countries are considered as established in CZ
  - So the general justification doesn‘t happen often in CZ
- Any procedure that an undertaking wants to be reimbursed must be in the national registry of the procedures
  - that is kept actual by the Ministry and State Institute for Drug Control (CZ HTA agency)

sect. VI. Q 4: **Shall the regulator link the justification process of new types of practices to the authorization process**

No – in CZ the authorization is for the use of a source for quite widely defined purposes (eg. general radiography or mammography) which are already generally justified. It isn‘t binded to indications – it is more clinical question and must be solved by the process of verification of new methods and by justification level 3. It is linked with reimbursement.

sect. VI. Q 4.1: **How to ensure – by this approach – an adequate execution of Art. 55.2 (a) in a MS with respect to the claim that new types of practices involving medical exposure are justified in advance before being generally adopted?**

by the connection with the reimbursement

sect. VI. Q 4.2: **How to ensure – by this approach – a harmonized execution of Art. 55.2 (a) in a MS?**

I am afraid that a harmonized execution is in these requirements unachievable

Generic Justification in CZ practice

- If the procedure isn‘t in the registry, the undertaking must initiate a process of adding it into the registry
  - First he must prove that the method is established
    - Either nationally by the described process
    - Or in other European country
  - Than a special Devices Comity meets
    - Members are the Ministry, HTA agency, Insurance companies, Professional bodies, (RP competent authority if medical exposures)
    - It decides about adding the procedure into the registry (so about reimbursing)
  - Or if it isn‘t with a new device, only the Ministry and HTA agency decides

sect. IV. Q 2: **By what measures can / must the regulatory process be supported:**

involvement of existing structures in the field such as HTA organizations

sect. VI. Q 1: **How can Health Technology Assessment (HTA) contribute to the justification process of new types of practices?**

fully

sect. VI Q 1.1: **What are potential weak points of the HTA approach?**

The ethical comity and HTA agencies may not understand the risks of ionizing radiation.

sect. VI Q 1.2: **How could these weak points be strengthened within HTA by Radiation Protection Authorities on a MS level?**

By setting a good cooperation between RP competent authority and HTA agency and Ministry of Health – in CZ is this cooperation still in development (good with the Ministry, not with the HTA agency yet)

CZ medical exposures cooperation

- Recently a good cooperation platform has been created (in 2015)
- Working Group on Medical Exposures under the Ministry of Health
  - Members:
    - The Ministry of Health
    - State Office for Nuclear Safety (RP Competent authority)
    - Professional bodies (radiologists, radiation oncology, nuclear medicine, medical physicists, radiographers, interventional radiologists, cardiologists, dentists)
    - Association of hospitals
  - Cooperation in
    - legislation of Ministry and RP competent authority
    - National Radiological Standards
    - Referral Guidelines (not yet – in future)
    - Clinical audits (legal base, authorization for external auditors, controls of external auditors, dissemination of information from the audits)
  - Exchanging information about
    - New legislation
    - New procedures and new devices
    - Other relevant topics

Questions from the discussion paper

sect. III. Q: **How broad is the scope of application of Art. 55.2 (c)?**

My opinion: very narrow - maybe some new special indication of therapeutically use of already established device that due to the patient state must be done quickly before the verification process starts

sect VII. Q 3: **How to regulate the interrelation of Art. 55.2 (c), addressing exposures not justified in general, but potentially justified on an individual basis, with Art 55.2 (a) and Art 55.2 (e)?**

Practically I cannot imagine a situation when the Art 55.2 (c) is applied.

sect. V. Q 1: **Could the information held by the manufacturer about the risk assessment and the clinical evaluation, being provided to obtain the CE marking, be made available for the application of Art. 78.2 Directive 2013/59/Euratom?**

Yes

sect. V. Q 2: **Could this information be available in the frame of the justification process related to a new class of medical practice, i.e. Art. 55.2 (a) Directive 2013/59/Euratom?**

Yes

Questions from the discussion paper

sect. VI. Q 2: **How can CE Marking contribute to the justification process of new types of practices?**

It should be very closely connected.

sect. VI. Q 2.1: **May CE marking according to the Medical Device Regulation serve as indication for justification of new types of practices due to the Council Directive 2013/59/Euratom?**

Yes

sect. VI. Q 2.2: **In this case, what is the potential impact of Art 78.2 Council Directive 2013/59/Euratom?**

Minimal, because a very similar thing is already required by Medical Devices Regulation

sect. VI. Q 2.3: **How to handle new radiopharmaceuticals by this approach?**

Normally as new drugs and new types of practice involving ionizing radiation.

sect. VI. Q 3: **Does the regulator have to define a "Standard Medical practice List", by which all ICRP level 2 justified types of practice are addressed, referring to the device, the radiopharmaceutical and the clinical indication and using a classification scheme of the different "types of medical practices"?**

No – it is not the regulator‘s job, it is more a clinical question