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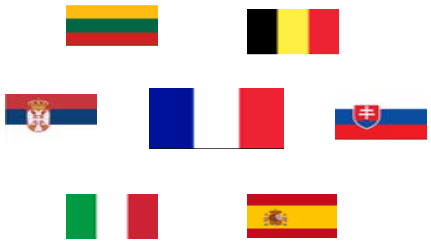
INNOVATIVE PARTNERSHIP
FOR ACTION AGAINST CANCER



EUROPEAN ROADMAPS

Access to Innovative therapies in cancer
Focus on immunotherapies

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INSTITUT NATIONAL DU CANCER

DETAILS OF THE SURVEY

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Objective :

- Highlight restrictions of reimbursement of innovative immunotherapies compared with their European marketing authorization and to understand the main factors leading to these restrictions;

- Identify existing early access programs for unapproved indications in Europe.

= Focus on check-point inhibitors and CAR-T cells

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DETAILS OF THE SURVEY

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Methodology :

- First questionnaire to iPAAC partners (12.2018) : questions regarding conditions of reimbursements and possible early access in their countries = replies from 23 partners;

- Second questionnaire to healthcare professionals, cancer institutes, medicines and HTA agencies, patients to get their opinion regarding the access to innovative immunotherapies = replies from 54 stakeholders.

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REIMBURSEMENT AND ACCESS TO INNOVATIVE IMMUNOTHERAPIES IN EUROPE

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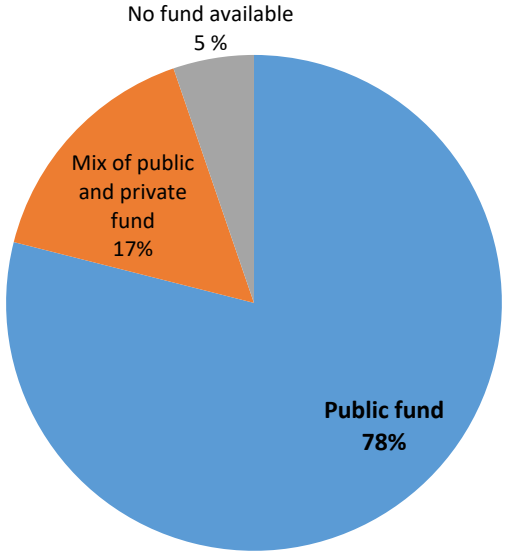
- Most of the countries who participated to the questionnaire have a public fund available to finance these innovative immunotherapies
  - No fund available : Moldova
  - Mix of public and private:

  Lithuania, Norway, Ireland



- In countries where there is a public fund available, there are no out-of-pocket costs for patients

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COMPARISON BETWEEN COUNTRIES REGARDING THE ACCESS TO INNOVATIVE IMMUNOTHERAPIES (12,2018)

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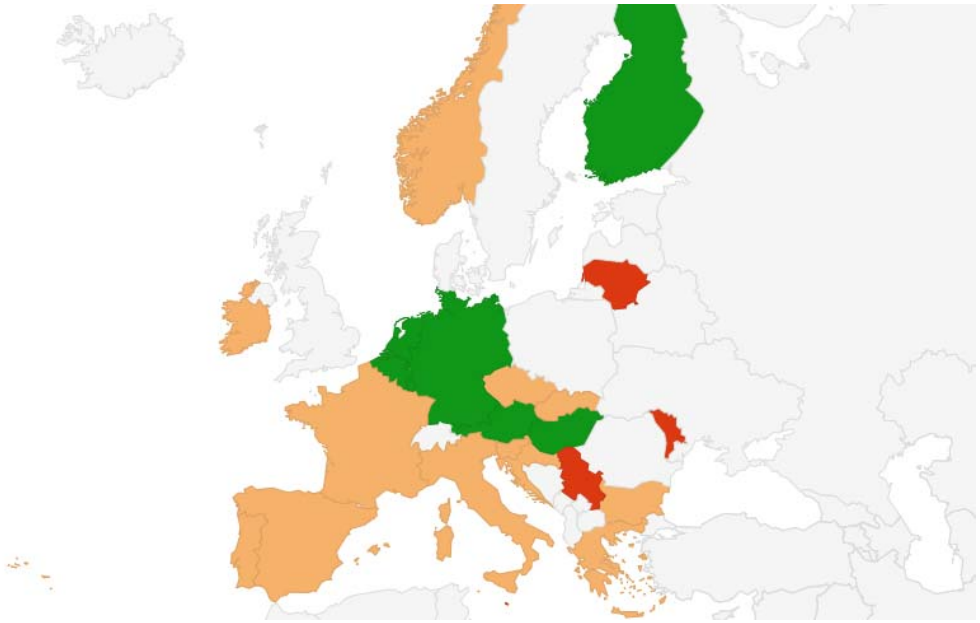

High access (≥ 15 indications/22 reimbursed with no restrictions compared to EU MA)

Moderate access

No access or very limited

- 4 countries had no or very limited access:
  - 2 countries did not have access to any innovative immunotherapies in terms of reimbursement for all types of cancer: Malta and Moldova.
  - For Lithuania, only the indications for lung cancer were assessed, but none of them were reimbursed;
  - In Serbia, only one immunotherapy was reimbursed: pembrolizumab for its indication in melanoma.
- 7 countries with high access
  - Germany: hospitals can order innovative therapies as soon as the MA is obtained
  - CAR-T cells: only Luxembourg & Germany had reimbursement in place without restrictions compared to EU MA 3 months post CHMP approval
- 12 countries with moderate access
  - For France: Assessment of reimbursement availability was performed based on the inscription on the list of sus (did not include other mode of financing (ex: ATU/post ATU)
  - Norway: Preapproved application to Norwegian Health Economics Administration (HELFO)
  - Many restrictions compared to EU MA for Slovakia, Croatia, Czech republic (but no details provided)

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IMMUNOTHERAPIES AND INDICATIONS WITH BEST ACCESS IN EUROPE

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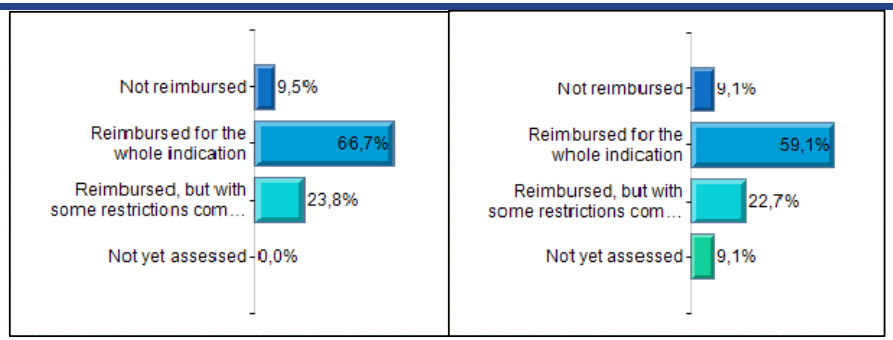
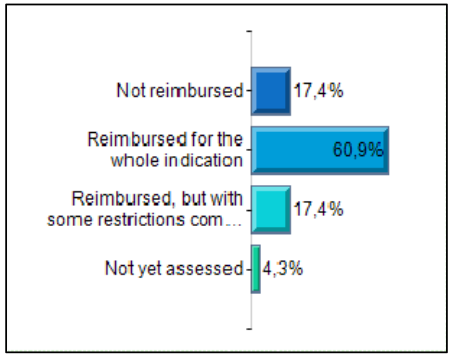
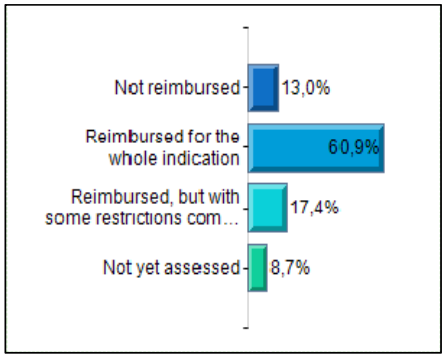
1) **Pembrolizumab** as monotherapy for the treatment of **advanced melanoma**: reimbursed in **90,5%** of countries
Only indication which was assessed in all countries/regions.



2) **Nivolumab** as **second-line** monotherapy for the treatment of advanced **renal cell carcinoma**: reimbursed in 82% of countries

3) **Nivolumab** as monotherapy for the treatment of **NSCLC** as **second line** (after chemotherapy): reimbursed in 78,3% of countries





4) **Pembrolizumab** as monotherapy for the **first-line** treatment of metastatic **NSCLC** in adults whose tumours express PD-L1 with a TPS ≥ 50%: reimbursed in 78,3% of countries

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REIMBURSEMENT OF INNOVATIVE IMMUNOTHERAPIES : CONCLUSIONS

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- Inequities were identified across countries and across indications.

- Three main factors leading to restrictions of reimbursement and thus limiting the access to innovative therapies were identified:

- Low level of scientific and medical evidence supporting marketing authorization;

- Missing direct comparison data with alternative therapies;

- High costs.

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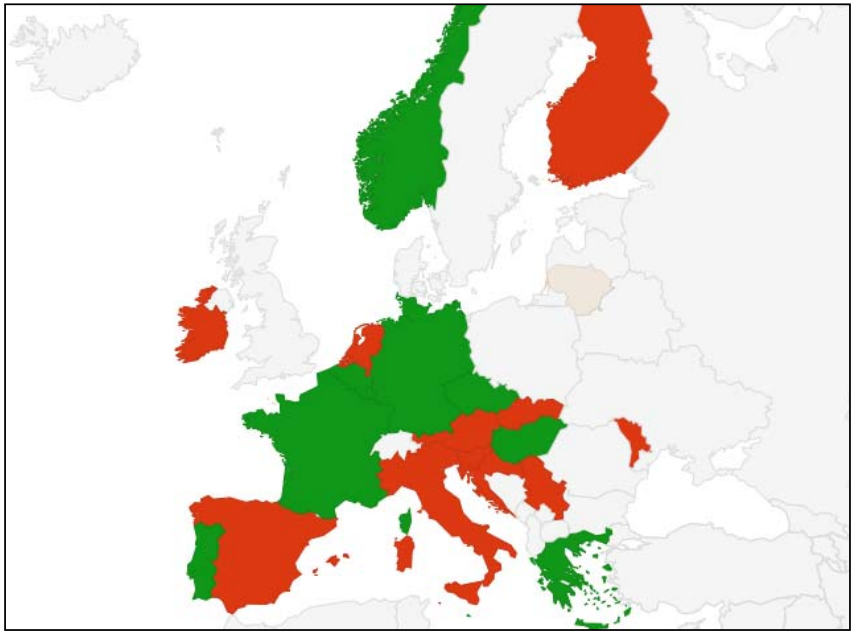
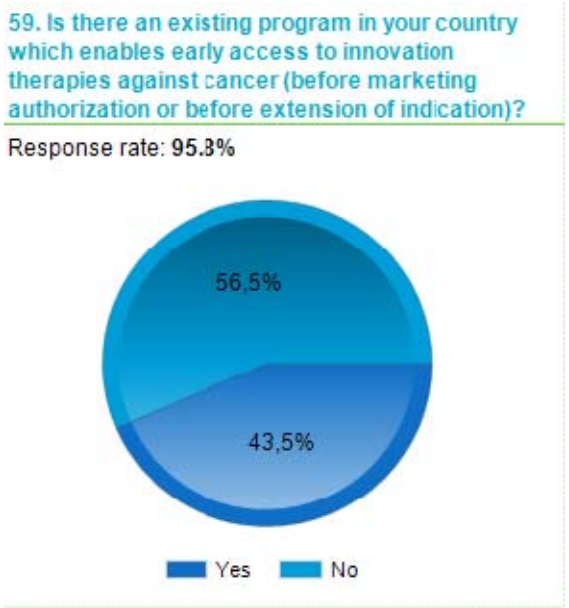
EARLY ACCESS PROGRAMS (I)

- About half of the countries (10/22, 45%) mentioned that they have an existing program enabling early access to innovation therapies against cancer (before marketing authorization or before extension of indication)



Note: N = 22 countries
(no reply received from Lithuania on this topic)



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EARLY ACCESS PROGRAMS

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- 80% of the stakeholders consulted who had such a system in place in their country were satisfied with their implemented system.

- Two main aspects stood out for an efficient implementation of early access programs:

  - Clear defined pathways and legal frameworks,

  - Strong discussion and collaborations among the different stakeholders.

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EXAMPLES OF EARLY ACCESS PROGRAMS

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- Portugal: “programa de acesso precoce” since June 2015: during the economic evaluation, drugs considered essentials are allowed to be used on a specific program without cost to patients, for an anticipated number of patients (managed by INFARMED, public funding)
- France: ATU, AcSé, RTU
- Germany: Several programs in place under the umbrella of the Federal ministry of education and research, federal countries and the German cancer research center. Financed by the German government.
  - German Consortium for Translational Cancer Research (DKTK), aim is to develop, to test and to apply innovative strategies in personalized oncology and also has a project focusing on cancer immunotherapy

- Compassionate use programs
  - Financing by the industry

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FRENCH NATIONAL CANCER INSTITUTE HORIZON SCANNING

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- Objectives :

- identify cancer drugs (and their associated biomarker) with high added value 12 to 18 months before their marketing authorization ;
- every year select 8 to 10 cancer drugs among high scoring drugs to organize their access (regulatory, financial and organizational aspects).

- Methodology:

- annual process based on a scoring system (25 criterias in 6 families)
- scoring done by the institute and also the clinicians :
- information and shared decision to selected the developpements with all the publics actors.

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