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Access in Ireland – some updates

Brenda Dooley , CEO, AXIS

Talk components

- Ireland’s evolving role and involvement in BeneLuxA
- The International Horizon Scan Initiative
- Developments re Medical Cannabis in Ireland & MCAP
- What’s news ; NCPE, HSE- CPU, Market Access

BeNeLuxA I and IHSI

BeNeLuxAI & International Horizon Scan Initiative

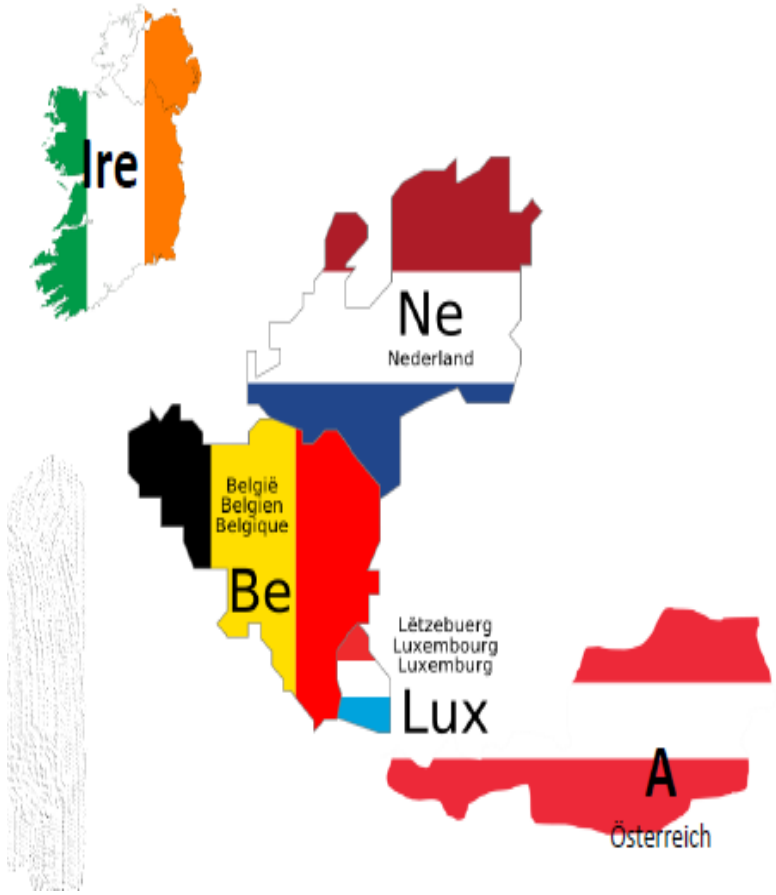
- The BeneluxA Initiative on Pharmaceutical Policy aims to seek successful ways of collaborating on pharmaceutical policy.
  - Horizon Scanning
  - Joint HTA
  - Information Sharing
  - Joint negotiations

- Establishing a systematic approach on horizon scanning for pharmaceutical products through IHSI.

- The Belgian and Dutch governments are leading the initiative - open to any interested country and not just BeneLuxA members.

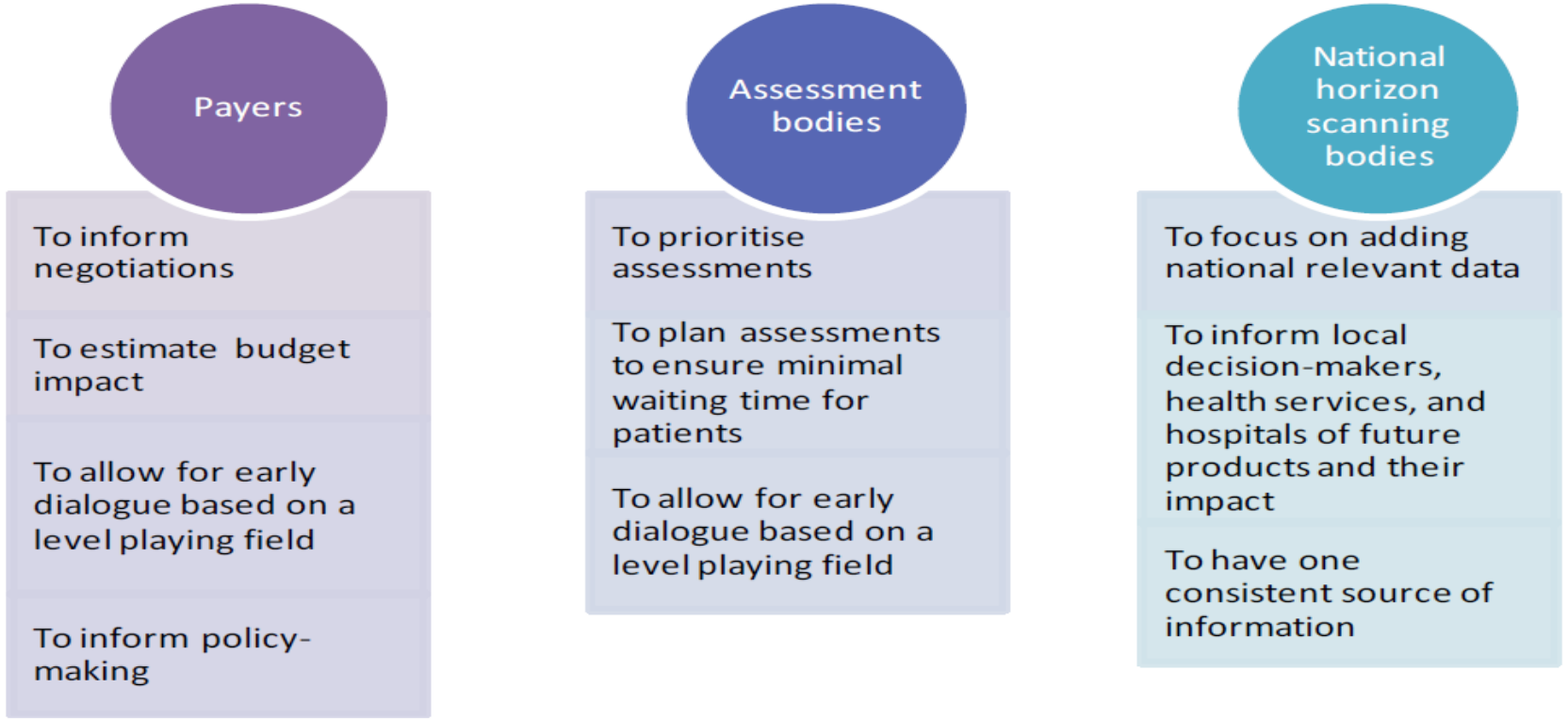
- An open market consultation was held with output published in Oct 2018.

- Industry Information Session, July 12, 2019 , Brussels.



International Horizon Scan Initiative

Figure 1: End-users of the HSS and possible use cases



Horizon Scanning System (HSS)

- According to IHSI which has now been incorporated and new board in place, the central HSS should perform the following tasks:
  - Collect data on new and emerging pharmaceuticals and medical technologies (including medical devices and accompanying diagnostics)
  - Focus the data collection on those products that are expected in the near future (approximately three years) aka filtering of the data.
  - To produce high impact reports that provide some insight into the future as to which products may have a significant impact on health care systems.
  - On a national level prioritisation may take place, but this is **not** part of the central database
- Data collected is owned by paying participants.
- Tender expected to issue end of Qtr 4 2019 for implementation in 2020.
- IHSI will not announce which countries have signed up to initiative until early Nov 2019

High Impact Analysis

Requirements for the impact analysis:

- The tenderer will deliver a High Impact Assessment (HIA) Report every 6 months
- The impact analysis will be performed through interviewing key opinion leaders in the field.
- The tenderer shall create a pool of medical experts, who will perform the HIAs based on previously collected data.
- At least 10 medical experts will perform the HIA per diagnostic area.
- Each expert in the pool shall have at least 5 years of experience as a medical specialist in the relevant diagnostics area and declare absence of any conflict of interests.
- Upon approval, the list of experts will be published on the HSS website.

Figure 4: high impact analysis method

- Organisation consequences
  - Health care use
  - Infrastructure
  - Impact on services delivery
  - Impact on disease mangement
- Health care costs
  - Population level
  - Patient level
  - Volume risk
- Innovativeness
  - First in class / availability of alternatives
  - Unmet clinical need
  - Patients / clinical demand
- Health benefits
  - Therapeutic value
  - Life expectancy
- Prevalence / incidence of disease
  - Patient population
  - Orphan designation

Medical Cannabis in Ireland

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5 September 2019

Outline

- Trajectory of Cannabis Legislation in Ireland
- Medical Potential
- Recent Legislation in Ireland
- Key Elements of MCAP Legislation
- Product Reimbursement

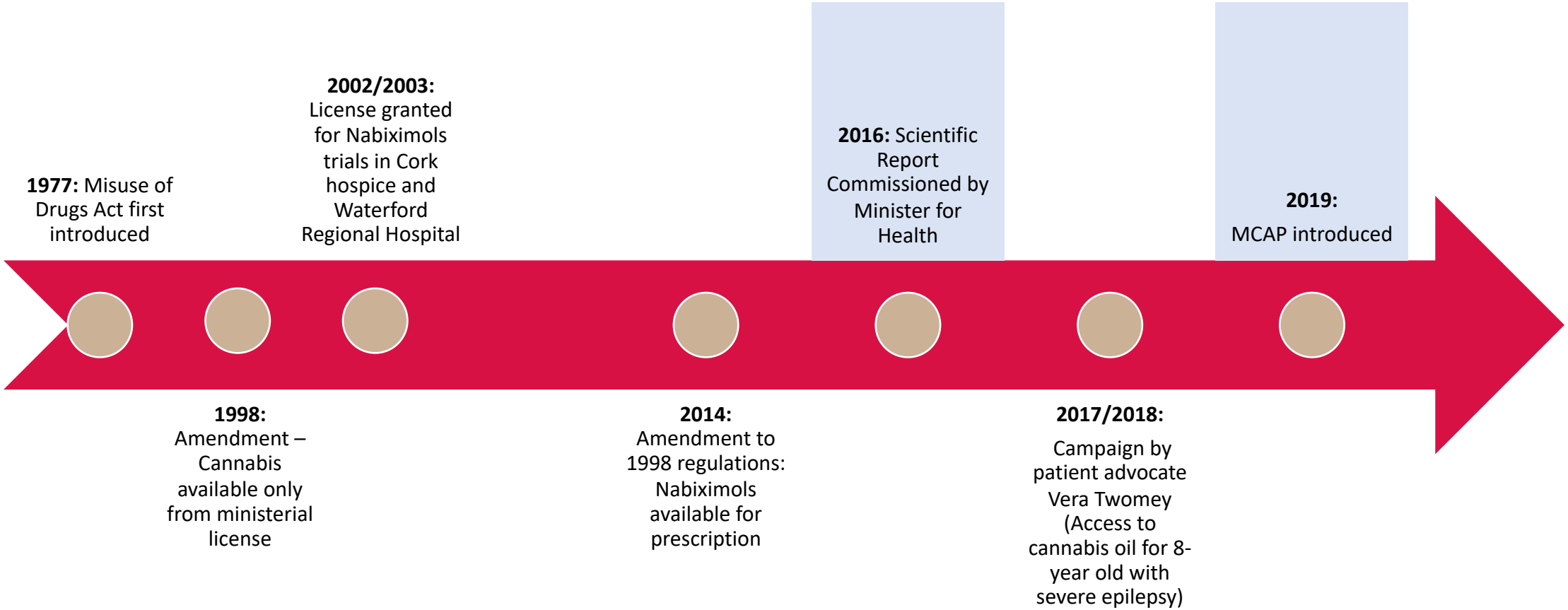
Introduction

- Medical cannabis – Use of cannabis-based products to treat disease or alleviate symptoms
- Considers both dried plant material and its derivatives and extracts
- Increasing number of countries providing pharmaceutical grade cannabis for treatment of chronic illness
    - USA (33 states)
    - Canada
    - Netherlands

Cannabis Pharmacology

- Cannabinoids – Bind to receptors in endocannabanoid system
  - Δ9-tetra-hydrocannabinol (THC) & Cannabidiol (CBD)
- Cannabis therapeutic effects dependent on THC/CBD ratio
- Positive THC and CBD interactions when delivered simultaneously
  - CBD lessens unwanted side effects of THC (psychosis and anxiety)
  - THC can increase CBD therapeutic effectiveness

Trajectory of Cannabis Legislation in Ireland



Medical Potential

- Scientific report commissioned by Minister of Health in 2016
    - Review of policies in other countries
    - Evidence of clinical efficacy
    - Legislative requirements to achieve access to medical cannabis

- Recommends use of medical cannabis for:
    1. Spasticity associated with multiple sclerosis (MS)
    2. Intractable nausea and vomiting associated with chemotherapy
    3. Severe, refractory epilepsy

- Paucity of research on clinical effectiveness of medical cannabis

Recent Legislation in Ireland – July 2019

- Medical Cannabis Access Programme (MCAP)
  - 5-year programme
  - Facilitate access to cannabis-based products for MS, chemotherapy-induced intractable vomiting and nausea and severe epilepsy
- Cannabis products accepted to MCAP
  - Schedule 1 Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019 – List of cannabis based drugs that meet MCAP requirements
  - Rescheduled from Schedule 1 to Schedule 2 of the Misuse of Drugs Regulations 2017 – Schedule 2 contains controlled drugs that have medical properties
- HSE will meet cost of products under the MCAP and supplied through community pharmacies

MCAP Expert Committee

Health Information and Quality Authority
- Dr Mairín Ryan (Chairperson)
- Dr Patricia Harrington

Royal College of Physicians of Ireland
- Dr Seamus O'Reilly - Medical Oncologist
- Prof Tony O'Brien – Consultant physician in palliative medicine
- Dr Peter Widdess-Walsh – Consultant Neurologist
- Dr Chris McGuigan - Consultant Neurologist
- Dr Bryan Lynch – Paediatric Neurologist

College of Psychiatrists
- Dr Mike Scully - Consultant Psychiatrist

The College of Anaesthetists of Ireland
- Dr Brendan Conroy - Pain Specialist & Anaesthetist

Irish College of General Practitioners
- Dr Des Crowley - General Practitioner

Pharmaceutical Society of Ireland
- Dr Cora Nestor

Community Pharmacy representative
- Keith O'Hourihane - Pharmacist

Royal College of Surgeons Ireland
- Professor David Smith - Ethicist

Patient representative
- Joan Jordan - European Patients Academy on Therapeutic Innovation
- Aileen Tierney

Health Products Regulatory Authority
- Elaine Breslin
- Vanessa Lyons

National Medicines Information Service
- Claudine Hughes - Chief Pharmacist

Department of Health
- Eugene Lennon - Principal Officer
- Eamonn Quinn, Maria Egan - Pharmacists
- Niamh O'Rourke - National Clinical Effectiveness Committee

Key Elements of MCAP Legislation

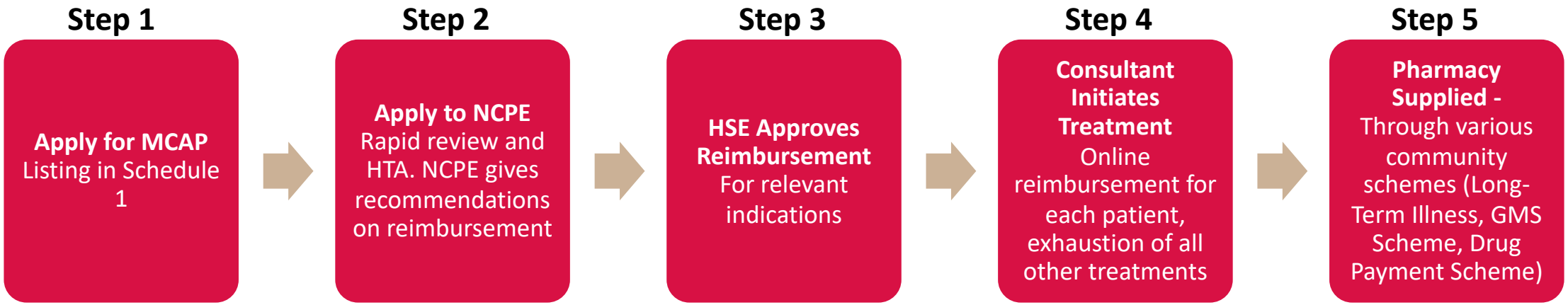
- Listing on the MCAP does not imply reimbursement
  - Still requires the standard processes of reimbursement

- Process for new cannabis-based products
  - Suppliers can apply to Heath Products Regulatory Authority (HPRA) to have products assessed for inclusion on the MCAP.
  - Requirement to have controlled drug and controlled drug import licenses
  - Licenses require annual renewal

Product Reimbursement – Procedures

- HSE will cover cost of all products prescribed under MCAP
    - Through existing programmes such as Long-term Illness Scheme, GMS (Medical Card) Scheme and Drug Payment Scheme
- Still require assessment by National Centre for Pharmacoeconomics
- Online reimbursement required for each patient
- Prescription procedure
    - Consultant initiates treatment
    - Standard treatments have been exhausted
    - Supplied by Irish pharmacies

Product Reimbursement - Procedures



HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Application for products to be considered for inclusion in Schedule 1 of the Misuse of Drugs (Prescription and control of supply of cannabis for medical use) Regulations 2019

On behalf of the Department of Health

MISUSE OF DRUGS ACT 1977
MISUSE OF DRUGS REGULATIONS 2017
MISUSE OF DRUGS (PRESCRIPTION AND CONTROL OF SUPPLY OF CANNABIS FOR MEDICAL USE) REGULATIONS 2019

Notes:
The Misuse of Drugs (Prescription and control of supply of cannabis for medical use) Regulations 2019 outline the legal framework and details of the Medical Cannabis Access Programme (MCAP) in Ireland. These Regulations enable the importation, prescribing and supply of cannabis based products or preparations, known as 'specified controlled drugs' in Ireland to those that meet the requirements of the Regulations and have been included in Schedule 1 of the Regulations.

In order for a cannabis based product to be considered by the Minister for Health for inclusion in Schedule 1 of the Regulation, companies must complete this application form. The following conditions of application must be met:

1. Every application must be accompanied by relevant supporting documents as detailed in section 5 of this form.

2. The application form, labels, leaflet and documentation must be in the English language.

3. A separate application form is required to be completed for each form and each strength of each product; however, several pack sizes of the same product can appear on the same application form.

4. Only cannabis based finished products requiring no further processing or manipulation can be considered for inclusion in schedule 1 of the Regulations.

Please complete all sections of the application form or mark them 'Not applicable' as appropriate. Incomplete application forms, or submissions missing supporting documents, will not be processed and may result in delays to the application process and the return or cancellation of the application.

Complete applications should be submitted to controlleddrugs@hpra.ie. The HPRA may contact the applicant with queries regarding the submission.

All products included in Schedule 1 of the Regulations will be also included in Schedule 2 of the Misuse of Drugs Regulations 2017. A separate annual licence is required to possess, supply or offer to supply, a controlled drug described in Schedule 2 of the Misuse of Drugs Regulations

Other updates

Updates on NCPE & HSE

- NCPE
  - Budget Impact Model template being finalised
  - new parameter tab template for running SA's
  - New Check in process for receipt of HTA's
- Change of Personnel for HSE-CPU Negotiation team
- Market Access Masterclasses 2020

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Questions ?

Thank you !

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