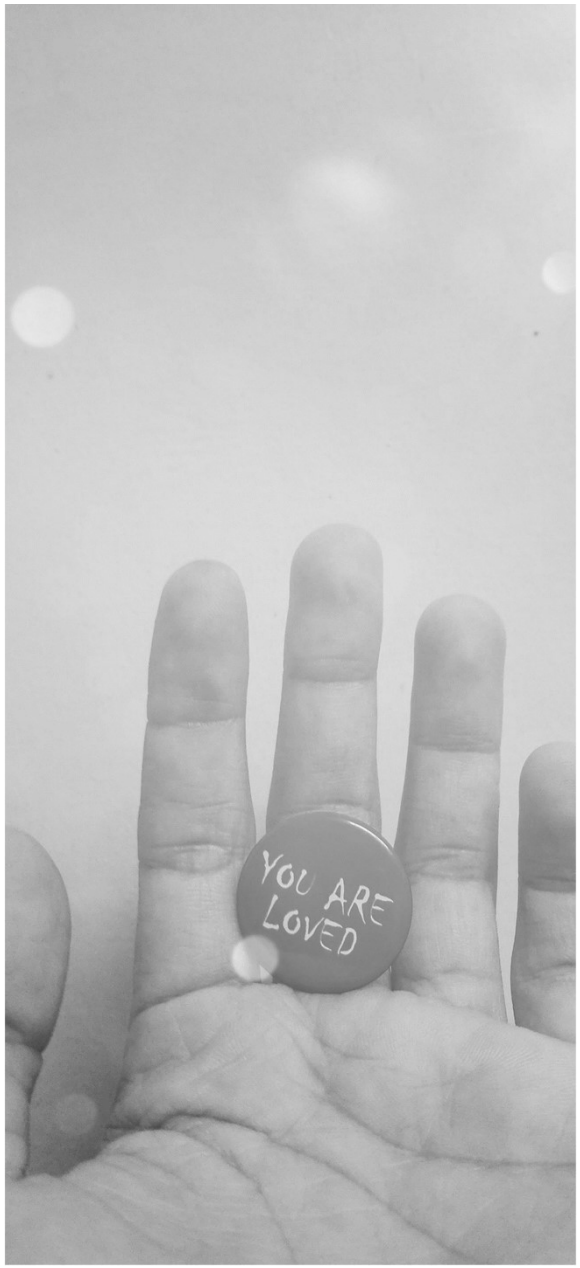
Innovative Medicines for Luxembourg

Lunch and learn
Legal review

December 14, 2021

Me Camille Saettel, Thewes & Reuter
Mrs Sini Eskola, EFPIA
Mrs Sonia Franck, APL



Practical informations

Lunch and learn is registred

APL will share the record on our youtube page

Questions and answers in the chat

You are invited to share your question in the chat

Material

The slide deck and the record will be available on our website

Mute yourself and rise your hand to ask to talk

Agenda

12:30 : Welcome (Sonia Franck)
APL in a nutshell, presentation of the speakers

12:35: EU pharmaceutical strategy 2021and outlook 2022
(Sini Eskola, EFPIA)

12:55: LU pharmaceutical strategy 2021 and outlook 2022
(Me Camille Saettel)

13:30: Q&A

13:50: Introduction to the Legal Task-Force and invitation for the Kick-off (Sonia Franck and Camille Saettel)

14:00: End

APL
Association Pharmaceutique Luxembourgeoise

Our mission

TO PROMOTE THE BEST HEALTH CARE BY ENCOURAGING THERAPEUTIC INNOVATION IN THE FIELD OF MEDICINES FOR HUMAN USE IN LUXEMBOURG

57 members / 19 members in task forces

+30 experts

ABBVIE, ALEXION PHARMA, ALK-ABELLÓ, ALLERGAN, ALNYLAM, AMGEN, ASTELLAS PHARMA, ASTRAZENECA, BAUSCH & LOMB PHARMA, BAYER, BEPHARBEL MANUFACTURING, BESINS HEALTHCARE, BIOGEN, BOEHRINGER INGELHEIM, BRISTOL-MYERS SQUIBB, CHIESI, DAIICHI SANKYO, DR. FALK PHARMA, EISAI, ELI LILLY, FARCO-PHARMA, FERRING, GALAPAGOS, GALDERMA, GEDEON RICHTER, GILEAD SCIENCES, GLAXOSMITHKLINE, GRÜNENTHAL, INCYTE BIOSCIENCES, IPSEN, JANSSEN-CILAG, JOHNSON & JOHNSON, KYOWA KIRIN PHARMA, LEO PHARMA, LUNDBECK, MENARINI, MERCK, MSD, NORGINE, NOVARTIS PHARMA, NOVO NORDISK PHARMA, ORGANON, OTSUKA PHARMA SCANDINAVIA AB, PFIZER, ROCHE, SANOFI, SERVIER, SWEDISH ORPHAN BIOVITRUM, TAKEDA, TEVA PHARMA, THERABEL PHARMA, TILMAN, UCB, VERTEX PHARMACEUTICALS VIFOR PHARMA, WILL- PHARMA, ZAMBON

Camille SAETTEL

Avocat à la Cour

Partner at THEWES & REUTER
IP / Healthcare / Life Sciences

Author of the book on Luxembourgish drug law published in February 2021 by LARCIER

Other video, slide deck of Me Saettel on APL Youtube channel and on APL website

Sini ESKOLA

Director, Team Leader
Regulatory, Drug development and Manufacturing

2014-NOW EFPIA – European Federation of Pharmaceutical Industries and Association
2008-2014 Global Regulatory Affairs Manager Industry
2005-2008 Executive Director of the Finnish Pharmacists Society

2000-2005 Pharmacist MSc, University Helsinki
2019-NOW PhD Candidate, Utrecht University

EU pharmaceutical strategy 2021 and outlook 2022

Sini Eskola
Director, Team Leader
Regulatory, Drug development and Manufacturing

EFPIA

European Federation of Pharmaceutical Industries and Associations

EU Pharmaceutical Strategy: Status Quo and Outlook into the Future





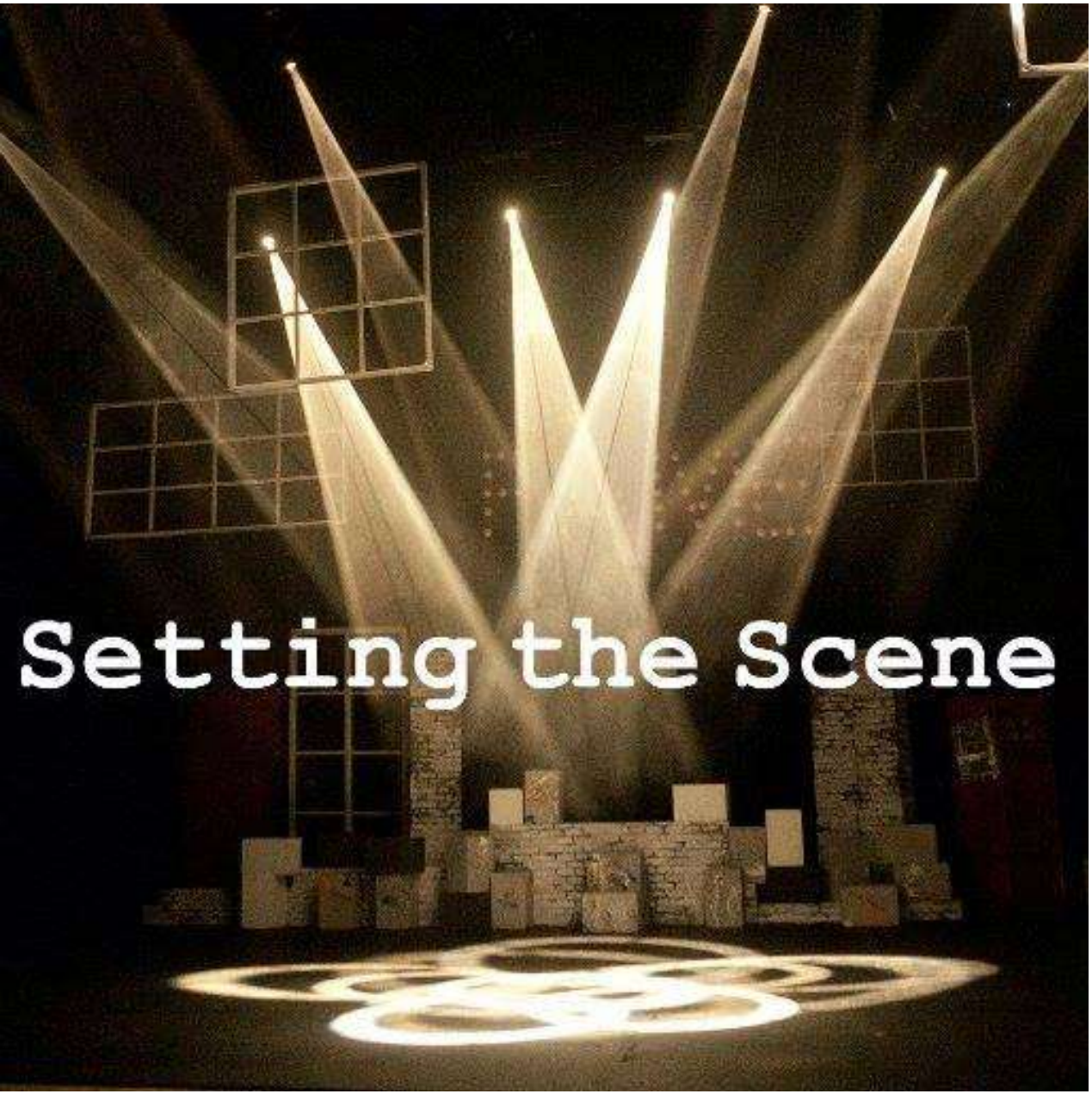

Presentation

APL Lunch and Learn, 14 Dec 2021

Sini Eskola

Who we are

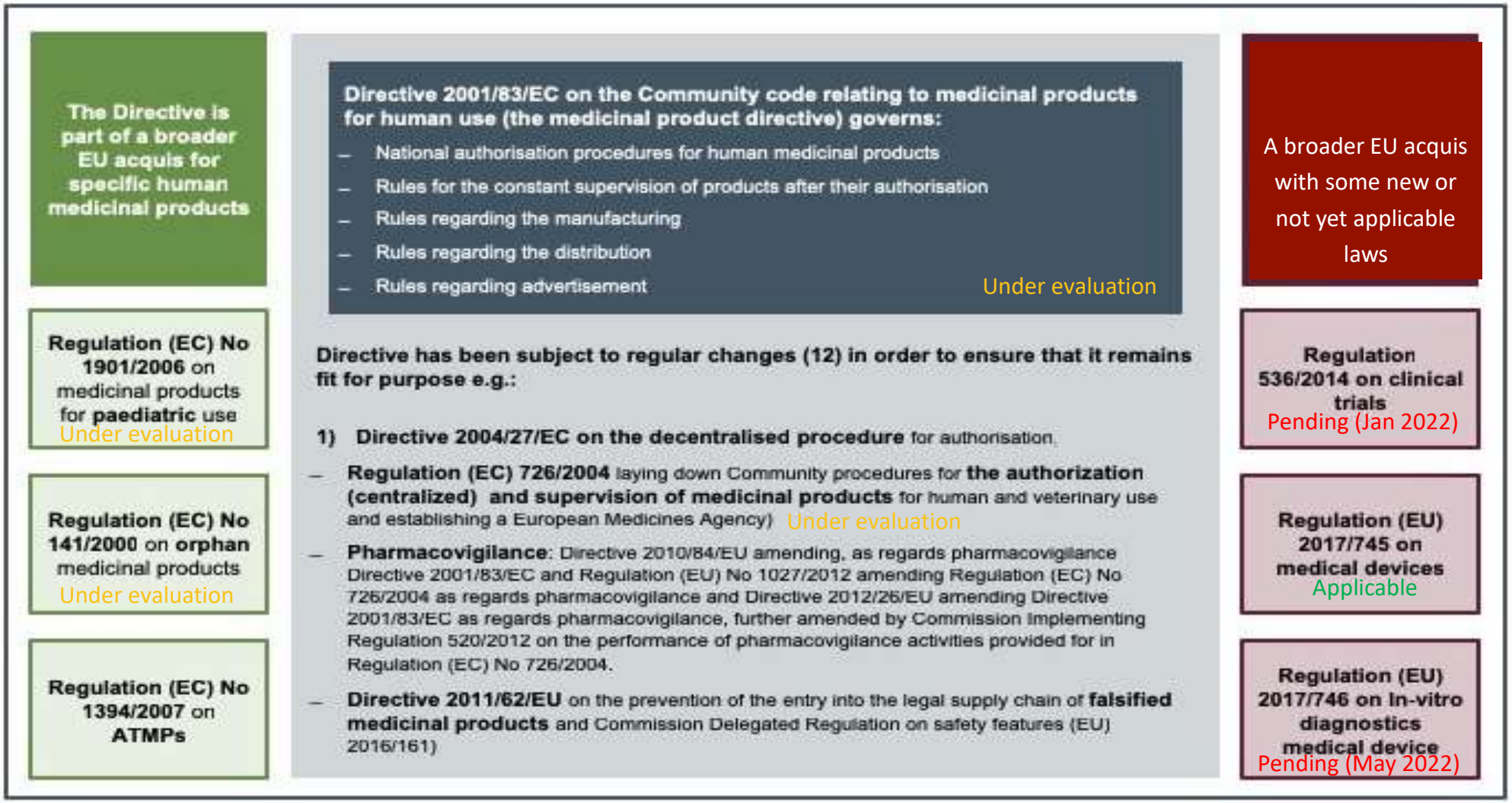
The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.



Today's objectives:

- Appreciate the complexity of the EU Pharmaceutical legislation (*Acquis*)
- Understand the aims of the EU Pharmaceutical Strategy and its' potential implications
- Raise awareness of innovative industry's point of view of optimal framework for medicines in the EU

EU Pharma Acquis for medicines (=jungle of regulations)



Pharmaceutical Strategy for Europe

"**Access** to medicines is a **huge issue**... there can be **no first and second-class citizens** in the EU... **inequalities** are simply **unacceptable**"

Stella Kyriakides, EU Commissioner For Health

"We want to **prioritise research and development** and **incentivise innovation** including on neurodegenerative and rare diseases and cancers"

EU Pharmaceutical Strategy – innovative industry perspective

Opportunities

- Shape a future-proof, world-class regulatory framework to lead the global innovation race
- Preserve strong and predictable IP incentive system, including for orphans, paediatrics and underserved areas
- Engage proactively in solutions on access, R&D cost transparency requirements
- Ensure that stricter obligations to supply or rules on withdrawals are proportionate and fit for purpose

EU Pharmaceutical Strategy – innovative industry perspective

Main risks identified

☹ Reduction of incentives (RDP, market protection)

☹ Conditionality of incentives (upon transparency of R&D costs and public funding, market launch, unmet medical needs)

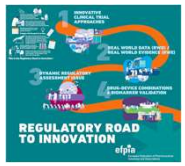
☹ Obligations: forced transparency of R&D costs/market launch, stricter obligations to supply/rules on withdrawals


MANAGEMENT
PLANNING
STRATEGY
THINK

Future-proof regulatory framework

EFPIA's Regulatory Road to Innovation

Goal: To drive an agile, competitive and world-class regulatory system in Europe and beyond that embraces advances in science, technology and medicines, accelerating access to innovative healthcare solutions and optimised patient outcomes.



Non-legislative:

Act now!

- Real world evidence
- Complex trial designs
- Dynamic regulatory assessment
- Drug device combinations
- Unmet Medical Need
- Digitalisation across product lifecycle
- Manufacturing chain & availability of medicines
- Revision of Variations Regulation (soft law)

Key "enablers" for achieving the desired changes:
(i) Dynamic Regulatory Assessment;
(ii) Digitalisation of the EU regulatory network operations and ways of working;
(iii) updates to the core **Centralised Procedure**

Legislative:

Proactive response to Pharma Strategy/legislation review

- Enable swifter, expertise-driven decision making
- Optimal use of expedited pathways
- Giving EMA accountability in the assessment of combination products and creating legal certainty
- Phasing out the paper PIL with an electronic PI

Stable & predictable IP incentive system

- Effective incentive ecosystem to ensure pharmaceutical innovation
- Broad understanding of unmet medical need, taking into account patient perspective
- Transferable exclusivity extensions to revitalise antimicrobial R&D
- Effective off-patent competition
  - Good procurement practices for off-patent biologics
  - EU-wide scientific recommendation on interchangeability for specific biosimilars
  - Limited Bolar exemption not applicable to pricing and reimbursement, tenders, etc.
- Holistic approach to tackle rare diseases
  - Improving the scientific viability of rare disease development
  - Modulation of OME according to predictable criteria

Access

- Working towards a system where pharmaceutical companies can file P&R applications in all EU countries within 2 years of EU market authorization
- Co-creating access solutions in partnership with the broader healthcare community, including Member States
- Creating an understanding and application of the value-based pricing
- Secure supply chains
- Harmonised definition of a shortage, to serve as a basis for a European reporting system based on a standardised format
- Transparency and understanding of patient demand, through timely (current and forward looking) ECDC epidemiological data
- More transparency on supply chains using EMVS data repositories

What to expect in the next five years?

- More than 50 different legislative and non-legislative actions are proposed as part of the EU Pharmaceutical Strategy:

- Review of:
  - The 2001 Pharmaceutical Directive (2001/83)
  - The 2004 EMA Regulation (746/2004)

Basic pharmaceuticals legislation, proposals to be adopted by Q4 2022

  - The 2000 Orphan Drugs Regulation (141/2000)
  - The 2006 Paediatric Regulation (1901/2006)

Commission proposals expected by Q4 2022 – NEW TIMING

Q4 2022: "Pharmaceutical package"

Unique approach on incentives, UMN, regulatory review, supply of medicines, etc.

efpia
European Federation of Pharmaceutical Industries and Associations

Thank you!






EFPIA Brussels Office

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LU pharmaceutical strategy 2021 and outlook 2022

Camille Saettel
Avocate à la Cour, Partner

THEWES ET REUTER

Agenda

I. From European Law to Luxembourg Law
   1. Clinical trials
   2. Medical devices

II. Focus on Luxembourg Law
   1. ALMPS (draft bill 7523)
   2. Draft bill 7383

Part I. From European Law to Luxembourg Law

Part 1

I. From European Law to Luxembourg Law

1. Clinical trials

- EU Regulation 536/2014 : will apply in 31 January 2022

Transition period (art.98) for Request for authorisation of a clinical trial filed between today and 31 January 2023: the clinical trial may be started in accordance with Directive 2001/20/CE

- Directly applicable in the Member States, do not need to be transposed into national law

However, certain topics subject to MS implementation

Do not miss trainings on CTIS

Part 1

I. From European Law to Luxembourg Law

2. Medical devices

- 2 EU Regulations

MDR : 21 May 2021
IVDR : 26 May 2022

- Directly applicable in the Member States, do not need to be transposed into national law
- However, certain topics subject to MS implementation

  - Distribution (registration?)
  - Advertising?
  - Information of users
  - Language requirements
  - Sanctions and fees
  - Requirements for clinical investigations
  - Etc.

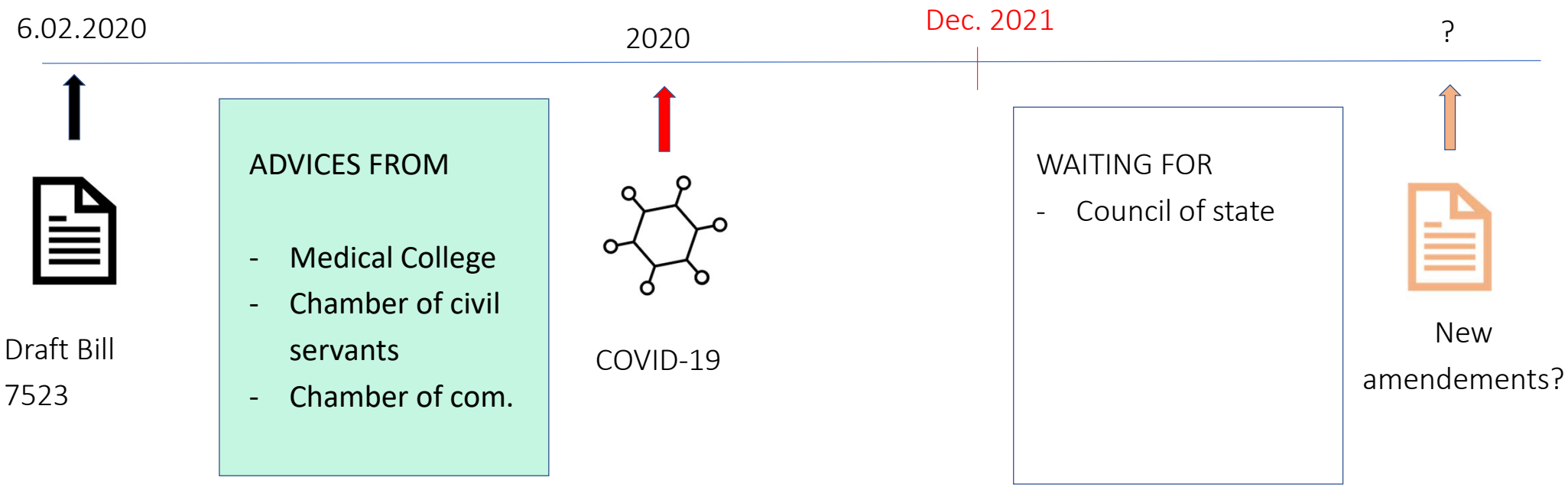
Part II. Focus on Luxembourg Law

1. ALMPS

Part 2

II. Focus on Luxembourg Law

1. ALMPS



Part 2

II. Focus on Luxembourg Law

1. ALMPS

Ongoing process

Current version of the draft bill :

- "Agence Luxembourgeoise des medicaments et des produits de santé" (ALMPS)
- the form of a **public independent body** (*établissement public*), with private employees (opposition of the Chamber of civil servant)

- Scope of jurisdiction (notably) :
  - Medicinal products for human use
  - Veterinary medicinal products
  - Experimental drugs
  - Medical devices (MD/IVD)
  - Cosmetic products (opposition of the Medical College)
  - Cells and tissues
  - Food supplement
  - "other health product" (*autre produit de santé*)

Part 2

II. Focus on Luxembourg Law

1. ALMPS

- Missions
  - Technical expertise
  - Support innovation in the biomedical and health technology sectors
  - Give advice to economic operators on regulatory matters
  - Evaluation of :
    - Manufacturing, distribution
    - Interventional / non interventional studies
    - Advertising
    - Post marketing surveillance

Part 2

II. Focus on Luxembourg Law

1. ALMPS

- Cooperation with the Direction of Health
  - Expertise (technical advice)
  - Pharmacist – Inspector of the Direction of Health may request assistance of the experts of ALMPS

Part 2

II. Focus on Luxembourg Law

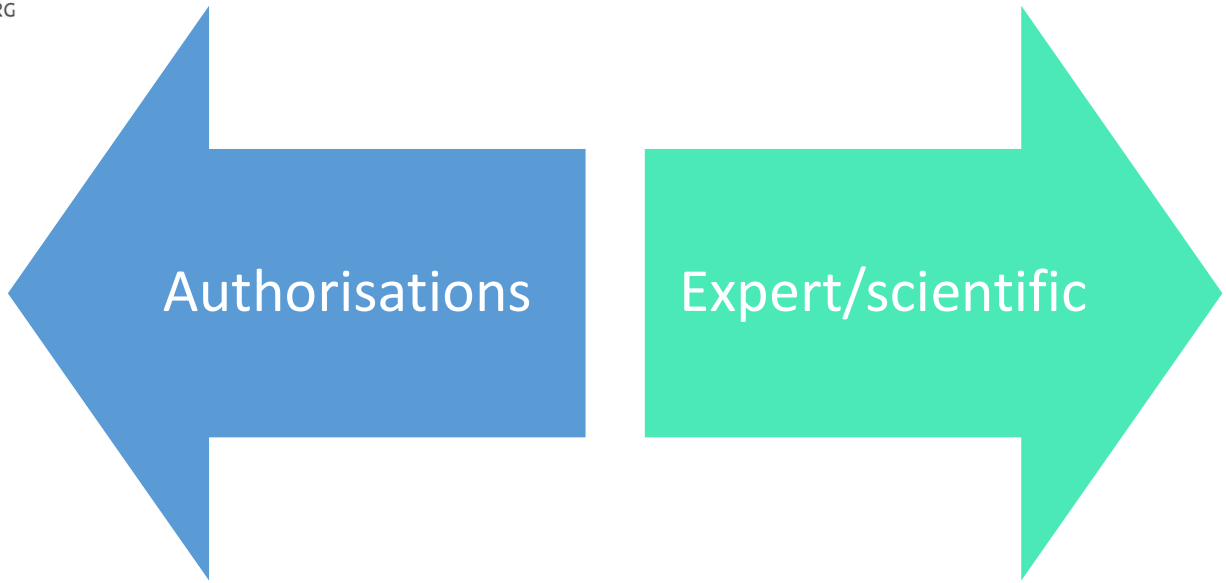
1. ALMPS

LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de la Santé

Administrative body

- Authorisations
- Controls

Work with the support and assistance of the ALMPS' experts



ALMPS

Scientific body

- Experts
- Inspections (with consent)

Limits :

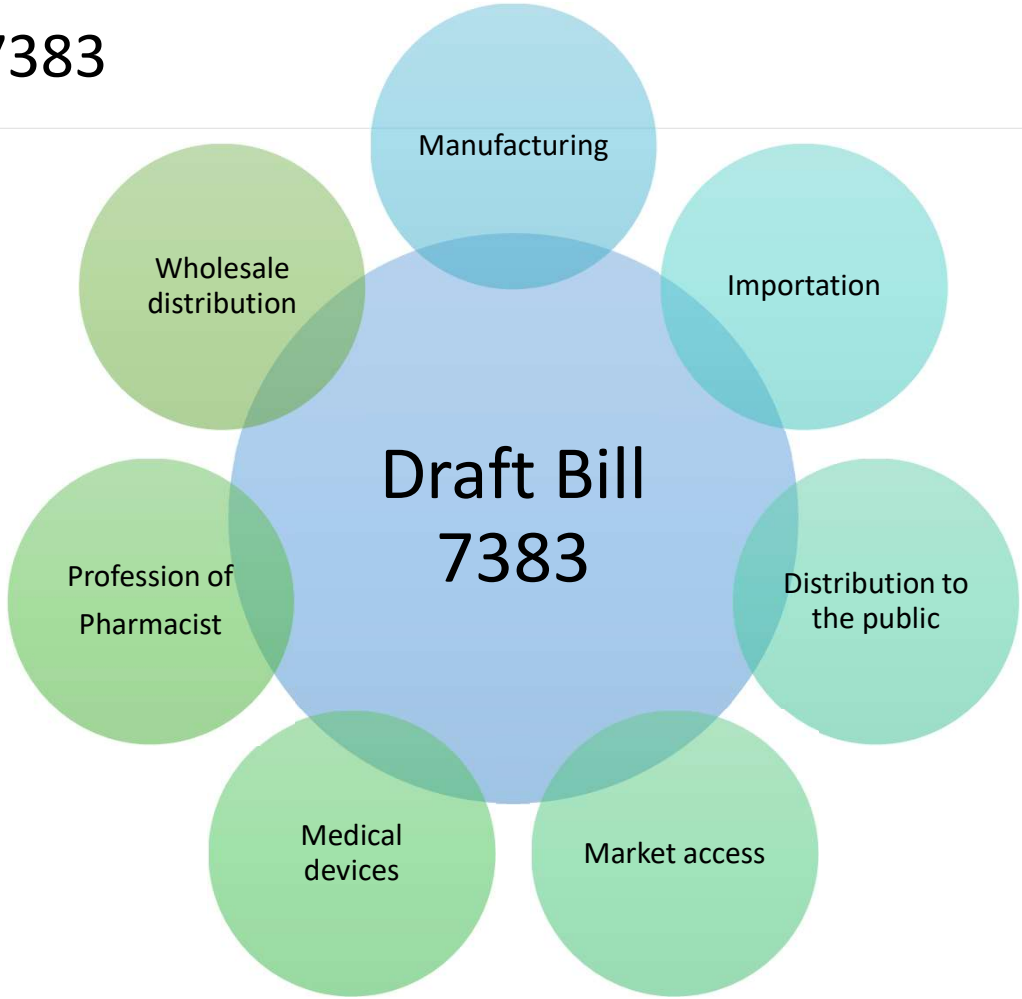
- No police and enforcement powers
- No authority to take decisions

2. Draft Bill 7383

Part 2

II. Focus on Luxembourg Law

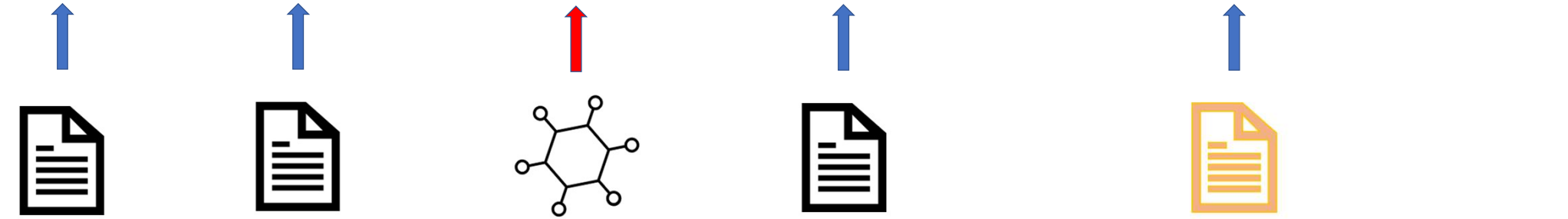
2. Draft Bill 7383



Part 2

II. Focus on Luxembourg Law

2. Draft Bill 7383



DB

Amendments

COVID-19

COVID Law

- Storage (« dépôt »)
- International crisis

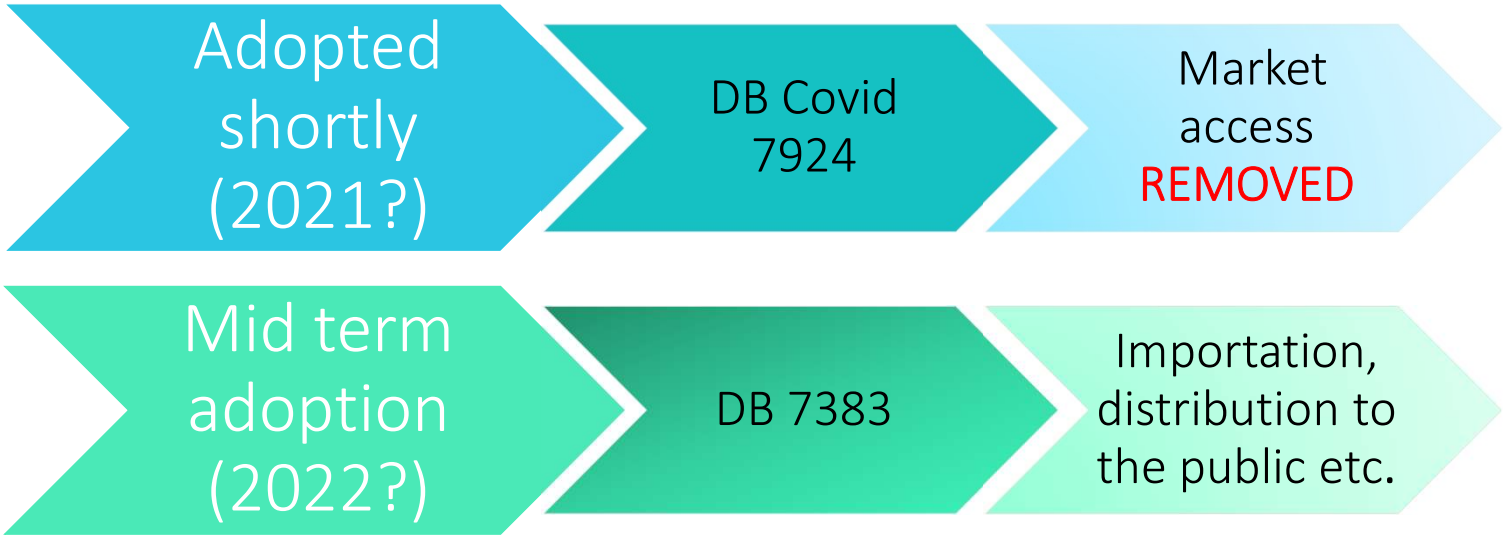
DB COVID 7924
Modifying 2020 COVID Law

- Market access / **REMOVED**
- Distribution of medicinal products

Part 2

II. Focus on Luxembourg Law

2. Draft Bill 7383 : upcoming reforms



Part 2

Upcoming reforms

a. Market access
b. Distribution of medicinal products
c. Importation of medicinal products

a. Market access

a. Market access

Off label use

Compassionate use

Part 2

II. Focus on Luxembourg Law

2.a Market access : off-label use (DB Covid 7924)

Medicinal product « off label » : medicinal product covered by a MA (centralised or Lux or abroad), but whose use does not correspond to one of the therapeutical indications of the MA.

- ✓ Clinical trial
- ✓ Pending MAA

Part 2

II. Focus on Luxembourg Law

2.a Market access : off-label use (DB Covid 7924)

Art. 5 of the Law of 1983

(1) The Ministry of Health may authorise, upon advice of the Director of Health, occasional and individual (nominative) prescription of a medicinal product "off-label" provided that :

1. The treatment cannot be performed in a satisfactory manner for the patient by observing the package leaflet of the medicinal product
2. The patient has been explicitly informed by the prescribing physician that the medicinal product is prescribed for a therapeutic use which is not mentioned in the package leaflet ;
3. The patient has given his written consent
4. The prescribing physician subscribed an insurance covering damages occurring for the patient

Part 2

II. Focus on Luxembourg Law

2.a Market access : off-label use (DB 7924)

(2) The request sent to the Ministry shall contain the rationale of the prescription outside the MA indications

+ duration
+ costs of the treatment

- DIFFERENCES with previous version of Draft Bill 7383 :

- SIMPLIFICATION (4 CONDITIONS vs 8), easier to understand
- Formal decision of the Ministry (case by case decision)
- No more provision on the delivery of medicinal product “off-label” (simplification)

Part 2

II. Focus on Luxembourg Law

2.a Market access : compassionate use (DB Covid 7924)

ART. 5ter
Occasional and individual prescription

ART. 5quater
Compassionate programme

Part 2

II. Focus on Luxembourg Law

2.a Market access : compassionate use (DB Covid 7924)

Art. 5*ter* of the Law of 1983

The Ministry of Health, upon advice of the Director of Health, may authorise the occasional and individual (nominative) prescription of a medicinal product, for compassionate reasons,

Which medicinal product?

Medicinal products covered by article 3 of Regulation 726/2004 (eligible to centralised procedure)

NO MA at all

- Ongoing Clinical trial or
- Pending MAA

Part 2

II. Focus on Luxembourg Law

2.a Market access : compassionate use (DB Covid 7924)

Art. 5*ter* of the Law of 1983 : Conditions

- The patient suffers from a disabling, chronic or severe disease, or an illness considered to be life-threatening, and cannot be treated with a medicinal product with MA
- Notification to EMA
- Patient informed
- Written **consent** of the patient
- This is not a clinical trial or investigation
- The risk/benefit profile is assumed
- The purpose shall no be the continuation of a clinical trial
- The treatment is placed under the **responsibility** off the physician
- The physician subscribed a specific **insurance** for the damages arising the the patient

Part 2

II. Focus on Luxembourg Law

2.a Market access : compassionate use (DB Covid 7924)

DIFFERENCES with previous version of draft bill 7383 :

- Simplification : Removal of the dual regime : special needs/imminent risk
- No provision on delivery
- No provision regarding the request (application form? To be determined in a GDR?)

Part 2

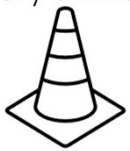
II. Focus on Luxembourg Law

2.a Market access : compassionate use (DB Covid 7924)

Art. 5*quater* of the 1983 Law : COMPASSIONNATE PROGAMME

The Minister may authorise, upon advice of the National Research Ethics Committee and the Direction of Health, the set up of a medical program for compassionate use (*progamme medical d'usage compassionnel*), provided that the medicinal product meets the requirement set out at article 83§2 of the EU Regulation 726/2004

Fully refers to the EU provisions, even for the definition of « compassionate programme »
Very similar to the individual authorisation for a compassionate use (art. 5*ter*)



CE raised in his advice the absence of clear difference between compassionate use programme (5quater) and occasional and individual (nominative) prescription of a medicinal product for compassionate reasons (5ter). FORMAL OPPOSITION

Part 2

II. Focus on Luxembourg Law

2.a Market access

Art. 5quiquines of the Law of 1983

Temporary authorisation of use of a medicinal product without MAA in order to fight against suspected spread of pathogens toxins, chemicals or nuclear radiation,

Waives the civil liability of MAH, manufacturer, physician, pharmacist etc.

b. Distribution of medicinal products

Part 2

II. Focus on Luxembourg Law

2.b Distribution of medicinal products

- **SHORT TERM : DB Covid (7924)**

- Wholesalers are allowed to supply medicinal products to the physicians, dentist, veterinary.

- List of the concerned medicinal products to be determined (by a GDR)

- Aims to allow the supply of vaccines directly to the physician's offices

Part 2

II. Focus on Luxembourg Law

2.b Distribution of medicinal products

MID TERM : DB 7383

Modification of Article 3 of the 1975 Law, containing the principle of the distribution to the public only in a pharmacy open to the public, in order to introduce 4 new exceptions to that principle, notably,

- pharmacist in charge of a pharmacy open to the public may be allowed to deliver medicinal products under a sealed envelope to people at home or senior's establishments

- authorized wholesalers may be allowed to deliver to the public compound health products (« *produits de santé composés* »)

c. Importation of medicinal products

Part 2

II. Focus on Luxembourg Law

2.c Importation

- Importation of medicinal product (outside EEE) : authorisation

Except “personal use”

- Importation of active substances : notification

ANY QUESTION?
Feel free to contact me

Camille SAETTEL
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Questions and answers

Sini Eskola
Director, Team Leader
Regulatory, Drug development and Manufacturing

efpia
European Federation of Pharmaceutical Industries and Associations

Camille Saettel
Avocate à la Cour, Partner

THEWES & REUTER
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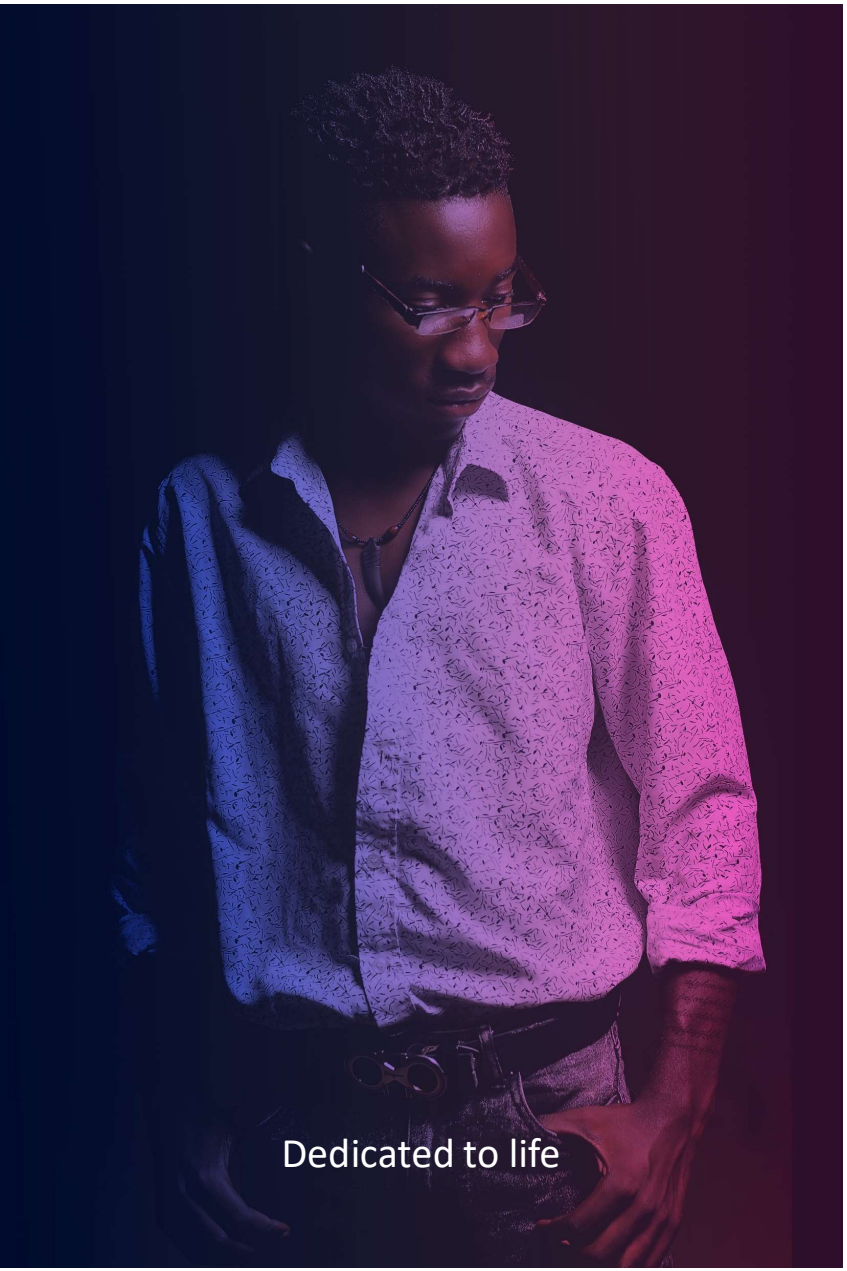

THE INNOVATIVE MEDICINES FOR LUXEMBOURG LEGAL COMMITTEE

Sonia FRANCK

Secretary-General

APL

Missions of the Industry legal committee

COMMUNICATE

SHARE

TEACHE

Mode of Operation

1 MEETING/QUARTER

+ IN CASE OF NEED

ALIGNMENT WITH TF

KICK-OFF : 25/01/2022 9:00-10:30

For who: Legal industry practitioner with part of Business in Luxembourg

Sonia FRANCK
Secretary-General

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