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Medical Products Agency and the biotech arena in Sweden

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Sweden
LAPPLAND
NORR-
BOTTEN
polcirkeln
JÄMTLAND
VÄSTERBOTTEN
ÅNGERMANLAND
DALARNA
HÄRJE-
DALEN
STÖDE
MEDELPAD
HÄLSINGLAND
GÄSTRIKLAND
VÄRMLAND
BOHUSLÄN
VÄSTMAN-
LAND
NÄRKE
DALSLAND
VÄNERN
UPPLAND
STOCKHOLM
GÖTEBORG
VÄSTER-
GÖTLAND
VÄTTERN
SÖDERMANLAND
HALLAND
ÖSTER-
GÖT-
LAND
GOTLAND
SMÅLAND
BLEKINGE
ÖLAND
MALMÖ
SKÅNE

Formal centre of Sweden- Stockholm central station

Real centre of Sweden-

Uppsala some 70 km north

Medical Products Agency

- Approval of new applications and variations of human and veterinary medicinal products. Laboratory testing and inspections of such products as well as general information to health care providers and public.
- Approval of Clinical trials
- Involved in control of medical devices, cosmetics and narcotics.
- Responsible for information to the public and profession on risks and treatment in case of acute poisoning by medicinal products, other chemical substances and biological toxins
- In total 870 employees, 336 of these directly involved in approval of clinical trails, new applications, PSURs and variations

Activities outside applications for approval of clinical trial, new products and variations

- In non-Corona times numerous F2F scientific advice meetings with applicants in relation to submission of CTs, MAA or variations
- In Corona times less numerous virtual meetings with companies on the same topics.
- Presentatations at scientific/ regulatory meetings (CASSS/ DIA etc.) as well as educational activities (workshops, lectures at Universities etc.)

Cooperation with fellow agencies within Sweden- main contacts

- National Board of Health and Welfare (Socialstyrelsen) is responsible for legislation in relation blood , cells, Stockpiling
- The Public Health Agency of Sweden (Folkhälsomyndigheten)- Recommendations for e.g. vaccinations, info on shortages etc., devices
- Health and Social Care Inspectorate (Inspektionen för Vård och omsorg; IVO) –overlap inspections of blood and tissue establishments

Health and Life sciences

- Govermental activity – Points for strategic collaboration which affects many national agencies and other parties
- One of four points are ”Health and Life sciences”
- To coordinate the work, clarify priorities and serve as a link between the goverment and the actors, a position of a coordinator at the national level has been introduced

Excerps from the strategy impacting MPA

- Effective process for implementation of new therapies
- Introduction of medical device legislation
- More company introduced clinical trials within Swedish medical care
- High quality of clinical trials
- Sweden leading actor in precision medicine

Consequences for MPA- Introduction of an innovation office

- A simple and clear contact point for discussions with the MPA
- Actively visualise MPAs activities related to innovation
- Increased analyses of activity outside Sweden
- Develop interfaces and platforms for dialogue
- Increase the regulatory understanding of scientists and innovators
  - Education and information activities
- Facilitate regulatory and scientific advice to all impated
  - SMEs
  - Academic groups.
- Network of contact points- not a formal organisational group
  - Flexibility in forming groups with the correct expertise.

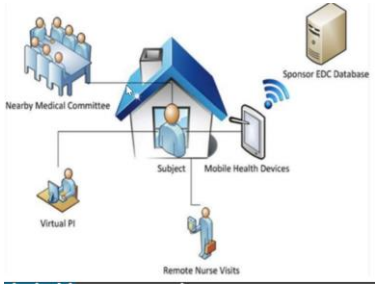
Increase regulatory understanding

- Understand the value of regulatory knowledge in development
- Lower hurdles to meet with the Agency
- Better understanding of regulatory requirement
  - Right first time
  - Avoid unneccesary trials or need for repetition of trials
  - Better applications → Fewer questions → Quicker approval

Examples of projects

- Three key projects with support from Vinnova, the national Agency for innovation
  - Virtual clinical trials
  - Addlife- competence centre for additive manufacucture
  - ATMP project.

Virtual clinical trials



- New method of collecting safety and efficacy data from clinical trial participants from study start-up through execution of trial to follow up
- Trials take full advantages of technologies (apps, monitoring devices) and online social engagement platforms to conduct each stage with the comfort of the patients. Allow patients living far away from centers to be included + rare diseases to be included
- Primary aim of preproject is to identify conditions to be fulfilled to initiate, plan and perform virtual trials.
- 5 different multidisciplinary groups including companies, CROs, CT units, researchers, trade associations, pharmacies etc.
- MPA, being responsible for approval and supervision of CTs, will lead the project and make sure that action is coordinated. Workshop planned and has gained great interest.
- Next step: IRL ?

Addlife-additive manufacture ” 3D printing”

- More than 20 dynamic partners in academia, industry and the public sector to support competence development in Additive Manufacturing for the Life Sciences
- Within the centre, collaborative research projects will be run through masters and PhD students, as well as dedicated research engineers.
- Current research themes within the centre include Equipment and process development, Bioprocess materials, Implants, Bioprinting, Medication, Implementation
- MPA contribute with regulatory knowledge regarding products falling under the Agency´s responsibility to allow clinical trials and future commercialization of these products as well as gaining experience in the field.

Advance therapies

- Project led by RISE (Research Institutes of Sweden)
- 15 partners across healthcare, industry, regulatory bodies and academia
- Aim: Sweden leading actor 2030
- MPA have recruited a ATMP coordinator to allow increased collaboration with national actors in relation to sharing information and knowledge. It also allows us to increase work with normative aspectes in collaboration with other Govermental Agencies

Advanced therapies at the Swedish Medical Product Agency:

National activities highlights

- Continuous interaction with other government agencies, healthcare professionals, the research communities and manufacturing industries, to maximize the availability of ATMP products with a positive benefit/risk profile for patients.
    - Deliver clear and timely communications to healthcare professionals and patients
    - Influence policy development at national and international levels
    - Build adequate capabilities to meet challenging scientific and technological advances within the field

Advanced therapies group within the Medical Product Agency

- National regulatory procedures for human and veterinary advanced medicines.

Advanced therapies group

Organization

- Multidisciplinary group (2008)
- Monthly meetings
- Intern scientific and regulatory forum
- Expertise:
  - Tissue & cells establishment inspectors
  - GMP inspectors
  - Quality, pre-clinical and clinical assessors
  - Veterinary medicines assessors
  - Pharmacovigilance assessors
  - GMO/ERA assessors

Advanced therapies group

- Promoting national strategies for a strong ATMP industry in Sweden and for internationalization.
- Promoting ATMP availabilitiy in health care
- Providing advice and clarification on ATMP-related general regulatory requirements.
- Active dialogue with other national agecies
  - National Board of Health and Welfare
  - Health and Social Care Inspectorate
  - The Dental and Pharmaceutical Benefits Agency
  - Swedish Association of Local Authorities and Regions

Advanced therapies group

- Early interactions on ATMP-related scientific and regulatory requirements in order to guide and support national ATMP innovation:
  - ATMP Sweden: national network of the Swedish ATMP field, promoting collaboration towards accelerated and effective patient solutions.
    - SweLife
    - CAMP
  - RISE (Research Institutes of Sweden)
    - National coordination + increased international contacts & collaboration
    - Increased ability for industrial development and manufacture of ATMPs in Sweden
    - Effective processes for research and accesability of cost effective ATMPs in Swedish healthcare.
    - Increased knowledge and securing future need for competence.

Swedish MPA inspectorate: ATMP-related national activities

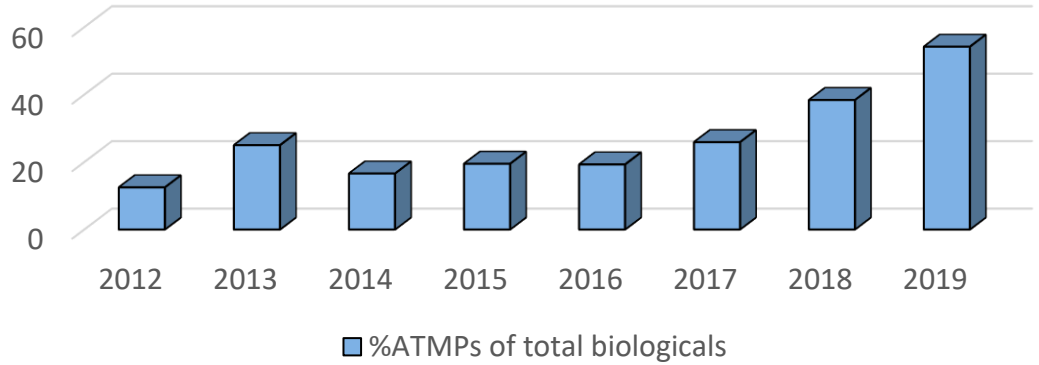
- GMP authorization
  - Time line: 90 days
  - Seven GMP authorized manufacturers in Sweden, mainly for CTAs and HEs.

- Tissue & cells establishments
  - Time line: 90 days
  - Eleven T&C establishments authorized in Sweden for collection of material intended for medical product development (MPA)
  - >50 T&C establishments authorized for collection of material intended for transplantation (IVO)

National procedures for human and veterinary advanced medicines, at a glance

Scientific advice (quality)

- Applicants (some at very early stage)
  - Academic
  - SMEs
  - Big Pharma

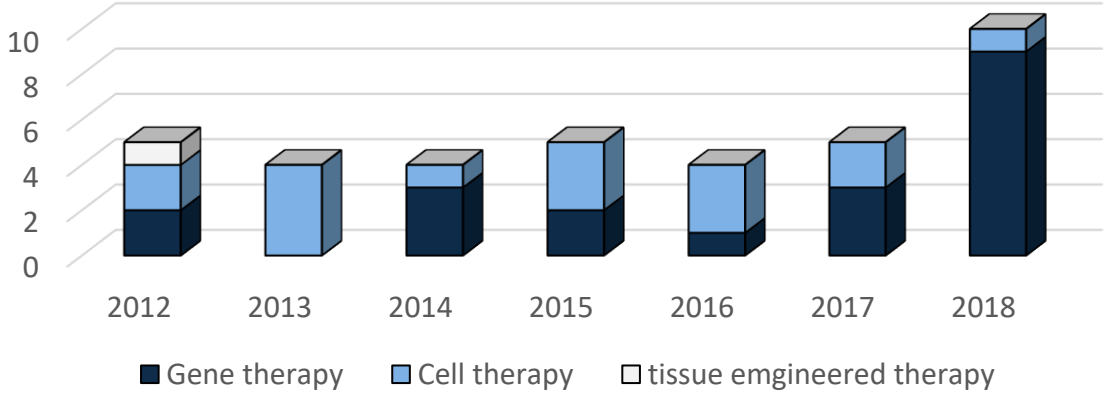


- Type of products:
  - plasmids,
  - viruses and viral vectors
  - somatic cell-based therapies
  - embryonic stem cell-based products and induced pluripotent stem cell-products
  - CRISPR-Cas technology
  - cells/tissues-medical device combined products
  - CARTs

National procedures for human and veterinary advanced medicines

Clinical trials

- Procedure timeline: 90 days
- Sponsors
  - Academia
  - SMEs
  - Big Pharma



- Product types:
  - Somatic cell therapy: mesenchymal stem cells or cells for immune therapy (e.g. DCs, NK or T cells)
  - Gene therapy: AAV vector based products, CAR T cells

National procedures for human and veterinary advanced medicines

Hospital Exception

- ATMPs which are prepared on a non routine basis and are used in a hospital, based on prescriptions for specific patients.
- Procedure timeline: 120 days
- GMP for ATMP applies
- Quality requirements similar to Clinical Trial Applications
- 2011-2020 → 12 HE applications, 6 ongoing
  - Cell based therapies (MSCs, chondrocytes, keratinocytes)
  - Ca 10 patients/ year
  - 5 years

Thank you- Questions?