EU regulatory Network
Challenges and Opportunities for Croatia
5th Anniversary of the ALMP

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Agence française de sécurité sanitaire des produits de santé

afssaps

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The European regulatory network has to address a wide range of qualitative challenges

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- Scientific developments: emergence of individualised therapies, biomarkers and predictive medicine, development of biological products not yet standardized …
- Regulatory changes: impact of new or looming legislation (clinical trials, ban on animal experimentation, variations ,new ICH guidelines …);
- Growing expectations from patients for speedy or anticipated access to products;
- New or resurfacing threats to public health: counterfeiting, unfettered sales on internet..;
- Growth of extra-EU activities of manufacturing and research, and complexification of distribution channels.

Three levels of involvement for a national agency

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- A widened scope of centralised matters resulting in more work for EMEA's staff but also more contribution from the national agencies: extension of the existing centralized procedure, coordination of European databases, additional authorization procedures,
- The persisting role of national agencies for managing crucial issues: collection of grassroots pharmacovigilance data, adaptation to specific national context of health-care systems and local expectations, dialogue with health professionals and patients, accountability to public opinion, government and parliament…
- In between, the necessary strengthening of cooperation, coordination and mutualisation of work within the network of national agencies: management of the mutual recognition and decentralized procedures, coordination of the national processes of authorization for clinical trials, work-sharing in such areas as assessment of PSURs…

Three major requirements to be a reliable and trusted contributor and remain within the network

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- Keep a high level of competence in the core business , by adjusting to scientific and regulatory changes : scientific monitoring, training, optimization of the combination of internal and external expertise,
- Secure a high degree of efficiency in the use of scarce resources : revamping of the organization, reengineering of processes (thanks in particular to workflow and common data bases), setting objectives and assessing their implementation,
- increase transparency to consolidate and enhance credibility and public confidence : handle of possible conflicts of interest among experts, put on line minutes of the scientific bodies, improve information on health products to health professionals and patients, develop cooperation with patients associations…

Some key points for a national agency : in the operational field (1)

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- Have life cycle approach of regulation of health products : beyond authorisation of clinical trials and registration of products, need to closely monitor use of products in real life,
- Secure permanent and smooth collaboration between all skills : evaluation, laboratory control and inspection (particularly GMP-GCP and PHVG inspection),
- Revisit on a regular basis operational strategies with a view to prioritising actions and foster optimal use of scarce resources : risk-based and public health added value approach
- Keep regular dialogue with stakeholders (health professionals, industry, patients associations) on operational issues,

Some key points for a national agency : in the management field (2)

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- Develop specific skills for a managing human resources : recruitment processes, evaluation schemes, life-long training,
- Set up efficient information systems : workflow, common data bases, move to digitalisation of at least the biggest procedures,
- Promote organisational flexibility to meet changing challenges,
- Rely on a sufficient flow of financial resources to both cover operation costs and necessary investments (data processing systems, adaptation of premises and equipment for laboratory control).

Afssaps : an autonomous public-health body in charge of regulating health products

- Public-health body working within the sphere of the Ministry of Health
- Operational independence in all fields of activity
- Under the steering role of government (Ministry of Health, with Ministry of Budget for financial issues) :
  - Allocation of resources,
  - Management board to approve strategic orientations,
- Wide mandate given to the DG of Afssaps to make necessary decisions on behalf of the State (about 80 000 decisions per year).

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Afssaps : a wide range of skills and products

- A broad array of activities :
  - Evaluation (before or after marketing authorization)
  - Inspection
  - Laboratory control
  - Information
  - Participation in the drafting of laws and regulation concerning health products, and enactment of mandatory good practices decisions,
- A wide spectrum of health products :
  - Chemical medicines
  - Biological medicines and other biological products
  - Medical devices
- Some other products :
  - Cosmetics
  - Tattooing products.

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Afssaps : a significant contribution to public health policies and programs

- Preparation for a possible human influenza pandemics,
- Contribution to conception or implementation of public health plans : cancer, hepatitis, road safety…,
- Expertise or operational support to the Health Ministry for coping with public health crises : Chikungunya in La Réunion, meningitis B in Seine Maritime, monitoring of inventories for sensitive products…,
- Need for a NCA to be seen not only as an efficient regulator but also as a body working for the sake of public health.

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Afssaps : some key figures (1/2)

- A workforce of about 980 employees, among which more than 200 in the labs, and 71% of women, 75% under public law contracts and 25 % of civil servants,
- About 1700 external registered experts: members of the about 50 commissions and working groups, or appointed for handling specific cases
- Three sites :
  - Saint Denis (headquarters and part of the labs),
  - Lyon (major centre for vaccine batch release in Europe),
  - Montpellier (various labs, mainly chemicals).

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Afssaps : some key figures (2/2)

- Budget of around 100 millions Euros, covered by
  - Taxes on pharmaceutical and medical devices turnover (40%)
  - Subsidy from the general State budget (5 – 15%),
  - Charges on various kinds of submissions (40%),
  - Other resources (10%),
- About 80 000 decisions per year :
  - 1 000 new marketing authorizations (70% of generics),
  - 15 000 variations,
  - 25 000 temporary use authorizations for medicines which haven't been yet authorized,
  - 1 300 authorizations for new clinical trials (≈1 000 for medicines).

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Afssaps : a strong involvement in the European network

- N°3 to 4 over the last 5 years for (co)-rapporteurships in centralized procedures
- Major OMCL for vaccines batch release, n°2 for control of centralized products (CAP)
- Front runner in the field of inspection, particularly in such areas as inspection of GMP, bioequivalence, GCP…
- Regular participation in most of the European working groups , whether scientific, regulatory or strategic (HMA meetings, EMEA Management Board).

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A long lasting and necessary commitment to international cooperation

- Urging need of cooperation between regulatory agences throughout the world, to cope with globalisation and safety challenges,
- Bilateral agreements with agencies of distant countries
- Significant involvement in multilateral work, particularly within WHO

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Strategics orientations available as a guidance for adaptation

- EMEA Road map, adopted by the management board in december 2004, soon to be assessed and revised,
- « Strategy paper », adopted by Heads of Medecines Agencies at the end of 2005, largely implemented to date,
- A number of NCA strategic plans at national level

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Strategic planning at Afssaps

- First strategic document ("projet d'établissement" - road map) for 2005-2007,
- First information system framework plan, for 2006-2010,
- First "performance contract" between the State and Afssaps (2007-2010) signed with the Health and Budget Ministries : a few strategic orientations, and for each of them, a few objectives with specific indicators and timelines,
- On that basis, a second "projet d'établissement" - road map (2008-2010) has just been adopted, by Afssaps management board.

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Conclusion

- The European Regulatory Network both rely on the contribution of all its members and can bring support and much of added value to each of them,
- I can confident that this reciprocal benefit will be showed once more by the case of Croatia, and that the Croatian Agency for Medicinal Products and Medical devices will very soon become a full and trusted member of the network.

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