Challenges and Practical Solutions to a successfu Implementation of the safety features in the hospital environment

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With a team of about 15,000 professionals and more than 3000 beds, **Lille** UH is the largest health campus in Northern Europe as a referral **university hospital** and a teaching, innovation and research center. Its pharmacy department (Pr P Odou) is comprised of 5 teaching pharmacists and 40 non-teaching pharmacists

Pharmaceutical activities are:

- Inpatient dispensation of medicines, medical gases, and medical devices,
- Outpatient dispensation of medicines not allowed in community pharmacies
- Clinical pharmacy & support for clinical trials
- Pharmaceutical preparations, chemotherapy reconstitutions & radiopharmacy,
- Reusable medical devices sterilization

The purchase & supply service of the pharmacy (Dr P Mazaud) acquires 290 millions€ of medicinal products (medicines and sterile medical devices) per year.

As expert in the UNI.HA division concerning « Health Products Dispensation » Dr P Mazaud is in charge of the deployment of FMD delegated regulations in hospitals

Summary

- State of readiness of the Directive to implement verification of prescription packs
- Practical issues and barriers encountered
- Challenges for the correct implementation
- How technology can support the implementation
- Evolution of the process in the future – plans to use digital tools

State of readiness of the Directive (from HOPE EAHP enquiry)

- A wide majority of Hospitals were not ready.
- There is a strong support from Hospitals Managers Federation and Pharmacists Representatives
- There is some support from the health ministry:
  - 1st NOTE of INFORMATION (February 8th, 2018)

    aiming at reminding in the community pharmacies and in the healthcare facilities of their obligations envisaged by the delegated regulations by fixing the modalities of safety devices
  - *SERIALIZATION* METHODOLOGICAL GUIDE "Struggle against the falsification of medicines in healthcare facilities».

    This guide gives a methodological help to Hospital Pharmacies which are hired in the implementation of the FMD regulation. It offers to bring a lighting in the healthcare facilities on step to be implemented
  - 2nd NOTE of INFORMATION (January 31st, 2018)

    Considering jobs which still remain to accomplish, the capacity of the software editors to include computer solutions, modifications to allow the interoperability of interfaces, necessary secured tools to be implemented to accomplish the stage of check and/or decommission prescription packs, in case of control of the NCA, the different actors will have to demonstrate they are actively aiming the goal, following an appropriate way, as soon as possible

EMVO Hospital Monitoring

		Detailed Base Values										Potential Indicators for Orientation					
		Healthcare Institutions	Hospital IT Systems	Hospitals	Hospital Pharmacies	Beds Public 2015	Beds Private non profit 2015	Beds Private for profit 2015	Beds Total 2015	Packs to Hospitals per year	Population in Mio	HCI/HP	Beds/ HCI	Beds/Hospital	Hospital Packs/ Person	Beds/ 1000 Persons	Packs/Bed and Year
	Source	National PM	National PM	WHO 2014	EAHP 2016	Eurostat*	Eurostat*	Eurostat*	Eurostat*	Quintiles IMS	Wikipedia						
1	Austria	50	4	290	48	45 097	11 223	8 818	65 138	28 994 943	8,8	1,0	1302,8	224,3	3,3	7,402	445
2	Belgium	180	80	187	172					20 648 511	11	1,0	0,0		1,9		
3	Bulgaria	200		336	73	41 043	0	10 890	51 933	44 211 371	7	2,7	259,7	154,6	6,3	7,419	851
4	Croatia	60		63	36	23 034	140	235	23 409	7 778 997	4,2	1,7	390,2	371,6	1,9	5,574	332
5	Cyprus			86		1 534	0	1 361	2 895		0,87			33,6		3,328	
6	Czech Republic	110		240	104	57 780	282	10 330	68 392	33 174 994	10	1,1	621,7	285,0	3,3	6,839	485
7	Denmark	8			8	13 415	655	310	14 380	7 653 052	5,7	1,0	1797,5		1,3	2,523	532
8	Estonia	24	2	30	25	6 038	170	316	6 524	2 341 012	1,3	1,0	271,8	218,2	1,8	5,018	359
9	Finland	130	6	259	82	22 552		1 302	23 854	7 952 354	5,5	1,6	183,5	92,3	1,4	4,337	333
10	**France**	**3000**	**200**	**3185**	**1835**	**253 364**	**57 384**	**97 497**	**408 245**	**140 714 319**	**65**	**1,6**	**136,1**	**128,2**	**2,2**	**6,281**	**345**
11	Germany	2000		3198	383	271 236	193 286	199 842	664 364	173 440 987	82	5,2	332,2	207,7	2,1	8,102	261
12	Greece			286	106	29 879	881	15 185	45 945	39 685 558	11			160,6	3,6	4,177	864
13	Hungary	170		180	111	69 427	2 055	187	71 669	13 298 396	10	1,5	421,6	398,2	1,3	7,167	186
14	Iceland	4			2	1 030	0	0	1 030		0,33	2,0	257,5			3,121	
15	Ireland	125		97	73					7 321 645	4,6	1,7			1,6		
16	Italy			1121	609	131 231	7 527	55 325	194 083	211 827 848	59			173,1	3,6	3,290	1091
17	Latvia	260	60	64	45	10 141	0	1 120	11 261	1 873 633	2	5,8	43,3	176,0	0,9	5,631	166
18	Liechtenstein					56	0	4	60		0,03					2,000	
19	Lithuania	44	45	93	39	19 963	0	273	20 236	2 860 424	2,9	1,1	459,9	218,1	1,0	6,978	141
20	Luxembourg	5	3	13	6					170 014	0,57	0,8			0,3		
21	Malta			9	5	1 933	0	108	2 041		0,43			226,0		4,747	0
22	Netherlands	300		272	108		70 310		70 310	14 173 939	17	2,8	234,4	258,5	0,8	4,136	202
23	Norway	32			32	14 956			14 956	6 467 682	5,2	1,0	467,4		1,2	2,876	432
24	Poland	1500		1102	38	184 549		8 818	193 367	50 061 078	38	39,5	128,9	175,5	1,3	5,089	259
25	Portugal	230		220	89	24 027	7 313	3 883	35 223	27 908 098	10	2,6	153,1	160,1	2,8	3,522	792
26	Romania	450		480	66	127 531	474	6 567	134 572	29 902 344	20	6,8	299,0	280,4	1,5	6,729	222
27	Slovakia	49	30	138	76					7 853 750	5,5	0,6			1,4		
28	Slovenia	28	5	28	31	9 214	0	101	9 315		2	0,9	332,7	332,7	0,0	4,658	0
29	Spain	600		736	250	95 015	16 754	26 599	138 368	165 915 246	46	2,4	230,6	188,0	3,6	3,008	1199
30	Sweden				37					10 761 064	10				1,1		
31	Switzerland			315	60					13 949 059	9			0,0	1,5		
32	UK	450	6		216	169 995			169 995	131 659 174	65	2,1	377,8		2,0	2,615	774
EU	**Sums**	10009	441	13026,4	4765	1624040	368454	449071	2441565	1202599492	520						

State of readiness of the Directive (from HOPE EAHP enquiry)

- Today, hundreds of Pharmacies for Internal Use (PUI) out of 2500 are connected to France MVO but very fiew (less than 20) are really equipped,
  - but most hospitals have prepared a plan to implement the regulation.
- There are mostly technical problems preventing the implementation:
  - 1/ the installation of the software connected to France-MVO is not operational in all hospitals;
  - 2/ producers and wholesalers are to slow in creating aggregated codes, as there are 250 million boxes of pharmaceuticals provided to hospitals; the message delivered by the EMVO on the aggregated code, without serious basis concerning security is complicating the relation between hospitals and pharma companies;
  - 3/ the lack of target funding by the French authorities adds to the perception that the directive is not providing any added value to the security of patients;
  - 4/ hospitals are worried about the consumption data by companies with headquarters outside the EU.
- *Major financial and technical obstacles. Software that let the hospital pharmacies connect to NMVO is still not installed. No budget has been allocated by French authorities to implement FMD in the hospital sector.*
- *French hospital pharmacists are aware and involved in the process. A large communication has been done through different pathways on FMD in France (hospital managers, trade unions, associations etc...). However, FMD implementation is progressing slowly and the causes are multifactorial.*

Practical issues implementation & Barriers encountered

- Performing a decommission scan for the whole supply at arrival simultaneously with physical check (quality & quantity)
  - **Incorrectly checked medicines (from every cause) cannot enter the pharmacy**
  - **Pharmacy stock and patient are protected**
- Performing a decommission scan for the whole supply when putting in stock simultaneously with check of location
  - **Wrong checked medicines (from every cause) go to quarantine area**
  - **Pharmacy stock and patient are protected**
- Performing a decommission scan at the delivery simultaneously with picking or/and destruction of package*
  - **Wrong checked medicines (from every cause) go to quarantine area**
  - **Patients are protected**

**The unique identifier should be decommissioned when the packaging is opened for the first time, as required by Article 28 of Regulation (EU) No 2016/161.*

Challenges for a correct implementation

- Performing a decommission scan for the whole supply at arrival = preferred scenario of 75% of hospital pharmacies*
  - **Integrated to reception process & supported by informatics (ERP)**
  - **Human costs differ widely on the way it's done: by pack or aggregated**
- Performing a decommission scan for the whole supply when putting in stock
  - **Integrated to stocking process & supported by informatics (WMS)**
  - **Human costs differ widely on the way it's done: by pack or aggregated**
- Performing a decommission scan at delivey
  - **Integrated to dispensing process & supported by informatics (every software of a same pharmacy)**
  - **Human costs depends on ergonomy & performance of the scanning system and the delay of transaction with NMVS**
- Main consequences
  - **Hi level performance of informatics (avaibility & continuity)**
  - **Hi level performance of human operators**
- Serialization and its consequences need adapted training programs and evaluation for
  - **Every pharmacy staff member**
  - **Information technician who cares of pharmacy softwares:**

***This is what UNI.HA has tried to help with**

Challenges for a correct implementation

- 6.6. Question and answers
  - Wholesalers could scan the packs in the hospital consignment to acquire the information on the UIs and **encode such information into an aggregated code**. Decommissioning would then be performed by the hospital by scanning the aggregated code. The only equipment needed for this operation would be a hand-held scanner and a computer (connected to the national repository).
- WG IV: Implementation of the Falsified Medicines Directive in the hospital setting
  - Decommissioning in hospitals can be accomplished by scanning individual unique identifiers or, if agreed with suppliers, by scanning aggregated codes. Although aggregation through the repository system will not be ready by 9 February 2019, some **manufacturers and wholesalers may be able to provide grouped unique identifiers to hospitals.**
  - The creation of data files should be based on a contract between the hospital and supplier. The exchange of the data file should be encrypted, secure , confidential and documented in the contract with the supplier **This is what UNI.HA has tried to help with**

How technology can support the implementation

- In Europe, between the batch by the producer and the reception at the level of the hospital, there is a "black hole" because there are not data of monitoring of the serialization, contrary to the United States where these data accompany the workflow.
- To overcome this lack, UNI.HA has looked for a solution which *allows to make easier the deployment of the FMD regulation & covers the whole need: interfaces suppliers immediately operational without additional development and insurance of compatibility with all existent hospital software solutions*.
- This solution
  - could be the first deck of hospital decommissioning process.
  - should transport the information digitized and secured from since the producer up to the hospital, by way of the different intermediate logistical actors.
  - would integrate the treatment of litigations (number in duplicate, number miss, wrong number, number already decommissioned, erroneous file)

Evolution of the process in the future – plans to use digital tools

- Make an opportunity of this regulation requirement!

- Use it to lead a re-eingineering of the dispensation process of medicines
  - as long as to record a serial number, so much to manage all marking information;
  - as long as to scan packs, so much to automate the economic management of the supply, even the stocking itself

- Use it to engage a full digitization of the dispensation process of medicines :
  - by the systems which allow to manage marking and supply movements;
  - by the dispensing robots and other automated systems
  - and by the way of automated dispensing cabinets in the wards.

- **Don’t think local, think global because french public hospitals are commissionned to be included in wide territory units = groupements hospitaliers de territoire (GHT)**