

I CSMS

Directive
Related Product
Information
(DRPI) project

ICSMS - DRPI

- Ø Six years ago the ICSMS-AI SBL considered how the input of data to ICSMS could be improved
- Ø This resulted in the idea of having a “Directive Related Product Information” (DRPI) approach:
 - § General information would apply to all Product Informations (PI)
 - § Information specifically required for each Directive or Regulation would be on dedicated “pages” displayed when the relevant EU legislation is selected

ICSMS - DRPI

- Ø DRPI will make data entry to the system more straight forward and allow all Directives to be included as fields would be designed to better fit with the Directive
- Ø allowing different: “risk classifications”; compliance scores; and uploads under each Directive being examined
- Ø The work to implement this concept was “put on hold” while the ICSMS system was rolled out to Member States and the movement of ICSMS to the Commission



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- Ø Since the roll out of ICSMS the EU Commission, in liaison with a number of ADCOs, have worked to identify some particular requirements and the best approach to take
- Ø This work will influence the approach taken for other Directives/Regulations in liaison with ADCOs and representative groups.
- Ø A project was agreed between the Commission and ICSMS-AISBL to provide information to assist this work

DRPI - project

Ø The aim of this project is:

- § To develop a data model that can accommodate the requirements for all the relevant legislation, so one PI can cover multiple investigations
- § To liaise with key groups to gather their information needs for a DRPI system.
- § Analysis of information to produce a user friendly model to assist the Commission to develop ICSMS to accommodate the wide scope of 765/2008/EC



ICSMS - DRPI

- Ø For this DRPI project the ICSMS-AISBL is funding the work on behalf of the EU Commission in close cooperation with the Commission's IT staff and Authority's market surveillance experts
- Ø The ICSMS-AISBL will proactively engage with ADCO's nominated experts, representative groups (where ADCOs do not exist) and other users of the ICSMS system.



DRPI Project – Next Steps:

- Ø Arranging contacts with planned ADCO meetings as far as possible during the second half of 2014 with a projected end date in the middle of 2015*
- Ø Producing a project plan that includes: specifications; milestones; tasks and a Gantt chart “timetable”
- Ø Producing “pop-up” guidance on the meaning and use of the various fields

*Detailed programming by the EU Commission is out of scope of this project and will follow our work.



ICSMS - DRPI

Ø The aim of this current project also includes some items not directly related to the DRPI approach, these are:

- § To help improve outputs statistics & quality tools
- § To advise on how ICSMS can assist market surveillance projects and their reporting of results
- § To hold further “feedback meetings” following on from the one held in Copenhagen in 2013 (first one is likely to take place in Vienna in early October 2014)