Summary of Substance Sessions at Task Force (13 December 2016) and built upon at the follow-up IDMP workshop (14 December 2016)

Whilst there has been a lot of discussion in the project so far regarding Products there has been little discussion regarding Substances. A breakout was undertaken at the Task Force to begin to consider the scope, process, responsibilities etc. Industry had prepared a position the day before as a straw man which was presented and then considered by the group. The recommendations from the Task Force were further considered the following day (These are marked in red). All of this will need to be further considered by the S&P subgroup; indeed there was a proposal to separate out the Substance Group and run it in parallel to the Product Group allowing appropriate expertise to be brought in and utilised effectively.

A number of key points were identified:

- It is planned that G-SRS is used as the basis for substance management in Europe
    - This will cover human and veterinary substance – the programme should deal with both
    - It must be operational before PMS is implemented (Substance/Specified Substance IDs will need to be available to create Product records)
- The need to be two main processes dealing with existing substances (substances already in authorised products) and new substances (those not yet in authorised products or are investigational substances in IMPs)
    - The plan is that investigational substances will be registered via SPOR processes although XEVMPD will still be used for Investigation Products
- The business cases for usage of Substance and Specified Substance data are not adequately defined
    - Work will be undertaken to define these business cases and determine which categories of information (Substance/SSG1/SSG2/SSG3) will be needed to support – and prioritised
        - There is concern amongst industry and some regulators that the scope is too large for a single implementation and it should be implemented in phases
    - This should be done in the context of defining a longer-term roadmap
    - At the follow-up session it was felt that there are two main use cases for Substance information for Iteration 1
        - To establish a Global PhPID for PV and e-Prescription usage
        - To establish a complete record of the manufacturers of active substances and improvements to processes to change this information (replacement of variation process) – but this could be achieved either by using SSG2 or assigning information in the Product record itself
- The target is that the Regulators will prepare the Substance and Specified Substance Information from their sources (databases, dossiers etc) for existing substances
    - MAHs may need to check some of the data for their actives and manufacturers
    - It will need to be defined who would be responsible for population of information gaps
    - MAHs would need to map their products to the correct Substance and Specified Substance IDs
- For new substances the target would be for the Sponsor/MAH to provide the data and supporting documentation to the regulator so that new IDs can be established
- The workload for this needs to be quantified

    - A pilot is proposed for e.g. 100 substances and related Specified Substances, undertaken by the regulators and for industry to check data and map this to products
        - There may be an additional pilot run by industry to assess what it would mean for them to locate and provide the information instead
    - Understanding this resource should elucidate what is feasible within the timeframe of Iteration 1
- In advance (or possibly in parallel) of this there should be:
    - Mapping of EU substance sources (XEVMPD EV Codes/ NCA databases) to FDA UNII codes (i.e. the content of the initial release of G-SRS) for
        - Substances
        - Specified Substance Group 1 (where needed e.g. herbals, allergens etc)
    - Priorities should be Actives first, followed by Non-Actives (although both would be required by the time SPOR for Products is implemented)
        - This would identify the gaps
            - Substances missing from the G-SRS database (this should be the highest priority for action i.e. establish Global IDs)
            - Missing data on substances that are in the G-SRS database (this should be a lower priority for action – less important at this stage than having a Global ID)
            - Misalignment of EU substances with those defined in G-SRS
- A population plan needs to be developed (based upon prioritisation and resources) and would include:
    - Data standards to be used
    - Processes to be operations
        - Existing substances
        - New substances
    - Responsibilities
    - Identification of limiting factors
    - Identification and mitigation of risks and dependencies on the availability of Substance information for Products
- The make-up of the Substance Group was considered to help identify the skill-set needed to progress the items above.