



Session 6: Incident Management

Recall and supply chain traceability

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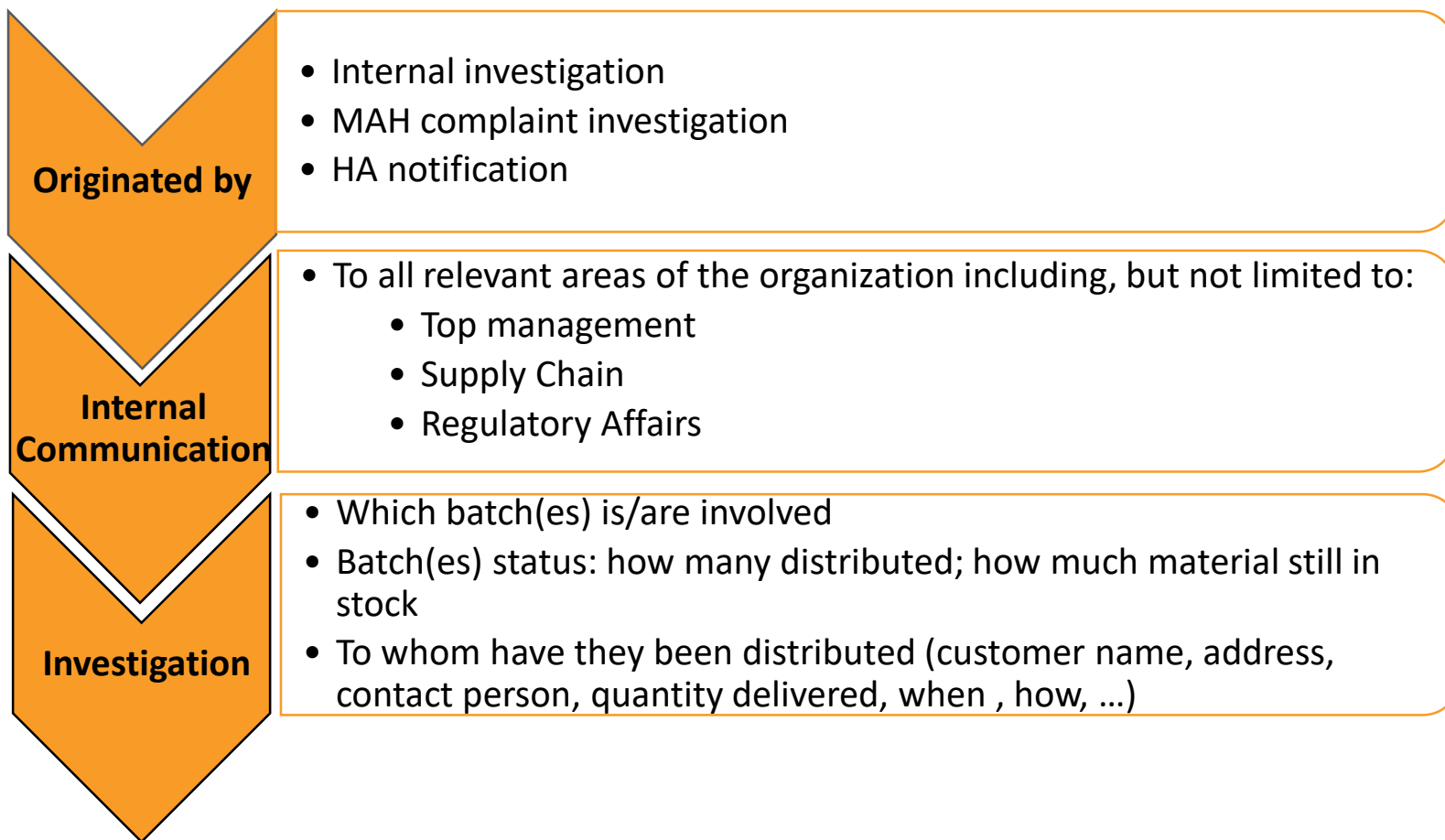
APIC

EMA Sartans with N-nitrosamine impurities
Lessons Learnt Exercise - Interested Parties Meeting
Amsterdam, 04. November 2019

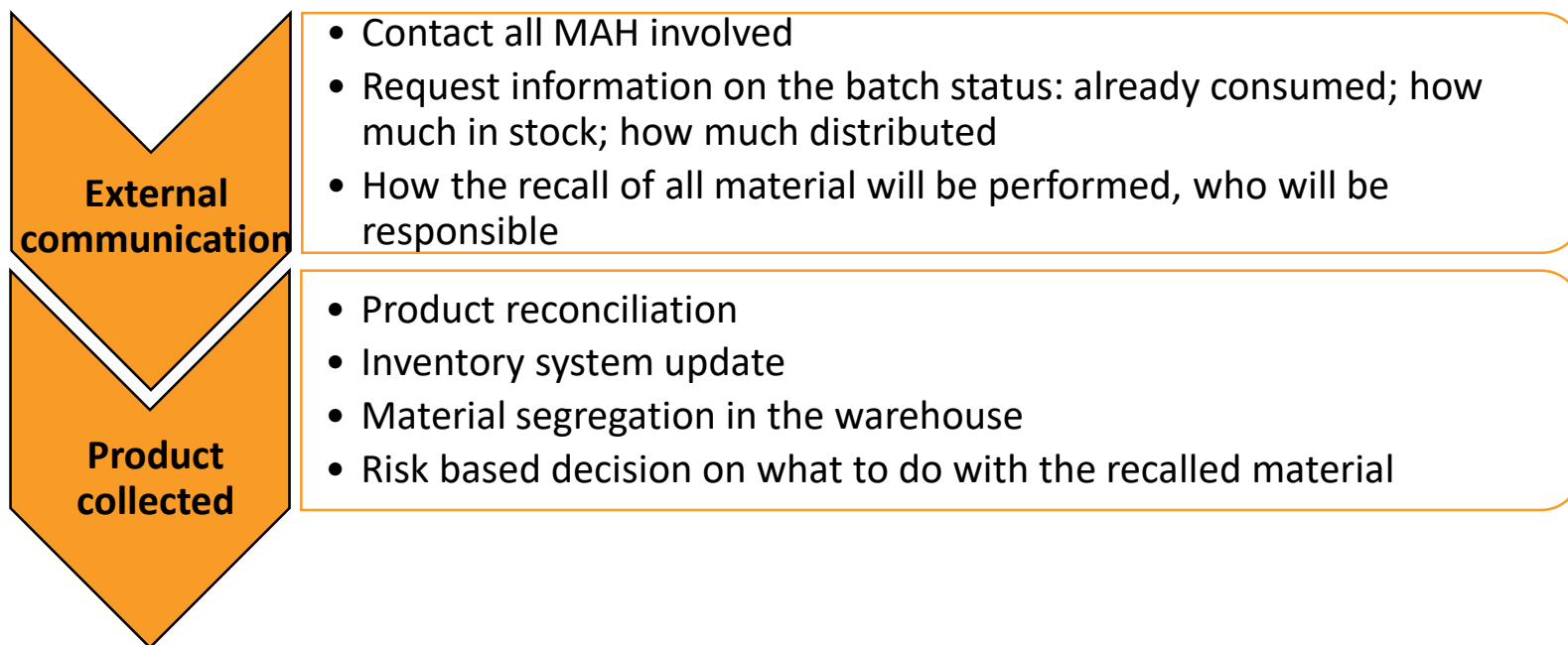


This is a joint industry presentation on behalf of the trade associations shown

Recall procedure



Recall procedure (cont.)



The process should not take more than 3 business days

* Responsibilities

- * The responsibilities within API manufacturer should be clearly defined in an internal procedure
- * The responsibilities between API manufacturer and MAH are defined in Quality Agreements

* Traceability

- * API traceability is required and retrieved in a timely manner:

API Manufacturer

should keep detailed information on:

- To whom the API was distributed (e.g. address of the receiving site(s), ...)
- Quantity shipped, date of shipping

MAH

should keep detailed information on:

- Origin of the API and when
- In which DP batches the API was used including quantities
- To where, when, how and quantity of the DP batch was distributed