Notes on Changes of the Marketing Authorisation Holder (MAH) or Notification of a New Co-distributor

Changes of the MAH or notifications of new co-distributors are to be notified as purely national notification in accordance with Section 29 Sec. 1 of the German Medicinal Products Act (AMG). They are not within the scope of the Commission Regulation (EC) No 1234/2008, instead a

The following documents must be submitted by the (present or new) MAH:

- Cover letter from which the MAH transfer / the notification of a new co-distributor can unambiguously be deduced.
- Application form „Anzeige einer nicht zustimmungsbedürftigen Änderung“
- Valid excerpt from the commercial register for the new MAH / co-distributor, unless it is already available at the Paul-Ehrlich-Institut.
- Updated national texts of the product information (editable word files; track changes and clean version)
- Declarations of the transfer of the MAH signed by the present and new MAH (not necessary for notifications of a new co-distributors))
- Statement on the implementation date of the MAH transfer / onset of the activity of the new co-distributor
  Note: In the absence of such statement, the submission receipt date at the Paul-Ehrlich-Institut will be taken as transfer date.
- Letter of authorisation if the submission is made by another company (consultant) on behalf of the MAH.
- Statement regarding possible changes in contact details of the Qualified Person for Pharmacovigilance (QPPV) and the location of the Pharmacovigilance System master File (PSMF)
  Note: The new MAH is responsible to verify whether the transfer of the MAH results in the introduction of a new Pharmacovigilance System Master File (PSMF) and Summary of the Pharmacovigilance system (sPSMF). In that case the new MAH has to submit a Type IA_{IN} notification according to category C.I.8 of the Classification Guideline (2013/C 223/01).

Specific requirements for blood components for transfusion and haematopoethic stem cells and parallel imports

The above mentioned requirements on the documentation also apply for blood components for transfusion and haematopoethic stem cells and parallel imports.
Deviant from the above, the following applies:

- There is no need to submit the above mentioned (see last bullet point) Type IA_{IN} notification as variations if these products are not within the scope of the Commission Regulation (EC) No 1234/2008.
- The specific application forms for blood components for transfusion and parallel imports have to be used respectively.