Following the review by the PDCO and the FWG, the choice of excipient may become the subject of 'key binding elements in the PIP decision', with a recommendation to replace or remove an excipient in the formulation, which would lead to the requirement to reformulate the drug product and has a high probability of affecting the overall development timeline for the product.[29]

Conclusion

The choice of suitable excipients is one of the key elements of pharmaceutical development for a pediatric medicinal product. When designing an age-appropriate pediatric formulation, excipients should be selected considering a number of different aspects outlined in this chapter.

The number and concentration of each excipient should be kept to the minimum necessary to achieve the required target product profile criteria, such as stability, bioavailability and patient compliance. Each excipient needs to be justified in terms of its function and quantity present in the dosage form, using a benefit-risk approach.

Where excipients with an identified risk cannot be avoided in the formulation of a particular pharmaceutical dosage form, the added value of the chosen pharmaceutical dosage form (and route of administration) should be balanced against the possible use of other pharmaceutical dosage forms and routes of administration that do not require the use of such excipients.

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