

France Assos Santé

La voix des usagers



Impact of medicines' permanent withdrawals on patients

HMA/EMA Workshop on shortages

Charlotte Roffiaen, 2 March 2023

www.france-assos-sante.org



- **Limited public info on medicines' withdrawals**
- **They can have an important impact on patients, especially when there are no or few competitors**
 - OLD DRUGS: Medicines indicated in bladder cancer: Mitomicyn C and intravesical BCG immunotherapy removed from the French market in 2016 & 2019 > Bladder ablations**
 - NEW DRUGS: Ibalizumab > Indicated in multi-drug resistant HIV > European market autorisation was withdrawn in Jan. 2023 at the request of the MAH > No alternatives available**
- **Revision of the pharma legislation: Patient requests**
 - Notification 12 months in advance**
 - Publication of withdrawals as soon as they are notified**
 - Facilitate the transfer of the medicine to a third party**