The underlisted safety variations have been submitted by Marketing Authorization Holders (MAHs) and approved by the Food and Drugs Authority in line with the Variation Guidelines for Allopathic Medicines.These safety variations are being shared with healthcare professionals and patients.

Safety Updates						
No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
1	Aluvia	Lopinavir/ Ritonavir	Side effects and Special precautions	Revsion of text to read "Hepatobiliary disorders: has been reported in patients on KALETRA therapy. Skin and subcutaneous tissue disorders: Toxic epidermal necrolysis, Stevens Johnson Syndrome and erythema multiforme have been reported. Cardiac disorders: Bradyarrhythmia has been reported.'under the sub-heading Post-Marketing Experience. Addition of text to read ''Renal and urinary disorders: Nephrolithiasis" under the sub-heading Post-Marketing Experience.	10-Jul-20	Abbvie Pyt Ltd
2	Arthrotec	Diclofenac/ Misoprostol	Special warnings and precautions for use	Revision of text to read ''Skin Reactions-Serious skin reactions, some of them fatal, including drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs, including diclofenac/misoprostol. Patients appear to be at highest risk for these events early in the course of therapy, the onset of the event occurring in the majority of cases within the first month of treatment. Diclofenac/misoprostol should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity. Allergic reactions, including anaphylaxis, have been reported with NSAIDs, including diclofenac/misoprostol, and have occurred without prior exposure to the NSAID.'' under this section.	26-Aug-20	Pfizer
			Undesirable effects	Addition of ''Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome)*'' as an adverse reaction under Skin and subcutaneous tissue disorders.		
			Pharmaceutical particulars	Revision of text to read '' Keep out of the sight and reach of children. Store below 30oC. '' under Special precautions for storage. Revision of text to read ''Arthrotec 50 is presented in cold formed aluminium blisters in pack sizes of 20, 28, 100 tablets. Arthrotec 75 is presented in cold-formed aluminium blisters in pack sizes of 20 and 100 tablets.'' under Nature and contents of container.		

3	Celebrex	Celecoxib	Therapeutic indications	Deletion of text "Relief of signs and symptoms of juvenile idiopathic arthritis (JIA) in patients 2 years and older with body weight greater than or equal to 10 kg" from this section.	26-Aug-20	Pfizer
			Posology and method of administration	Deletion of entire text '' Juvenile Idiopathic Arthritis (JIA)-Celecoxib has been studied in JIA patients 2 to 17 years of age. Safety and efficacy of celecoxib in children have not been studied beyond 6 months duration or in patients with body weight less than 10k g (22 lbs), or in patients with active systemic features (see section 5.1 Pharmacodynamic properties, Clinical Studies)'' and a table on pediatric dosing under the sub-heading Children.		
			Method of Administration	Revision of text to read ''The sprinkled capsule contents on applesauce, rice gruel or yogurt are stable for up to 6 hours under refrigerated conditions (2-8 °C)'' under this section.		
			Special warnings and precautions for use	Revision of text to read '' Serious Skin Reactions- Serious skin reactions, some of them fatal, including drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of celecoxib. Patients appear to be at highest risk for these events early in the course of therapy, the onset of the event occurring in the majority of cases within the first month of treatment. Celecoxib should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.'' under this section.		
			Pharmaceutical particulars	Revision of text to read "Capsules (200 mg) contain lactose monohydrate, sodium lauryl sulfate, polyvidone, croscarmellose sodium, and magnesium stearate. Capsule shells contain gelatin, titanium dioxide; ink contains ferric oxide E172 (200 mg capsule).'' under List of excipients. Revision of text to read ''Store below 30 oC. The sprinkled capsule contents on applesauce, rice gruel or yogurt are stable for up to 6 hours under refrigerated conditions (2-8 °C). The sprinkled capsule contents on mashed banana should not be stored under refrigerated conditions.'' under Special precautions for storage. Revision of text to read ''Celecoxib is available in blister packs of 200 mg x 10's, 20's, 30's and 100's respectively.'' under Nature and contents of container.		

4	Kaletra	Lopinavir/Ritonavir	Side effects	Revsion of text to read "Hepatobiliary disorders: has been reported in patients on KALETRA therapy. Skin and subcutaneous tissue disorders: Toxic epidermal necrolysis, Stevens Johnson Syndrome and erythema multiforme have been reported. Cardiac disorders: Bradyarrhythmia has been reported.'under the sub-heading Post-Marketing Experience. Addition of text to read ''Renal and urinary disorders: Nephrolithiasis" under the sub-heading Post-Marketing Experience.	10-Jul-20	Abbvie Pyt Ltd
5	Novir	Ritonavir	Side effects	Addition of text to read ''Renal and urinary disorders: Nephrolithiasis" under the sub-heading Post-Marketing Experience.	10-Jul-20	Abbvie Pyt Ltd
6	Ponstan	Mefenamic acid	Special warnings and precautions for use	Revision of text to read "Skin Reactions- Serious skin reactions, some of them fatal, including drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs, including mefenamic acid. Patients appear to be at highest risk for these events early in the course of therapy, the onset of the event occurring in the majority of cases within the first month of treatment. Mefenamic acid should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.'' under this section.	26-Aug-20	Pfizer