Sexual dysfunctions associated with proton pump inhibitors: insights from VigiBase, the World Health Organization pharmacovigilance database

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Supplementary Table 1. MedDRA terms included in the SMQ "sexual dysfunction" (narrow search).

Preferred term (PT)
Anorgasmia
Dyspareunia
Ejaculation delayed
Ejaculation disorder
Ejaculation failure
Female orgasmic disorder
Inadequate lubrication
Libido decreased
Loss of libido
Male orgasmic disorder
Oestrogen deficiency
Orgasm abnormal
Premature ejaculation
Sexual dysfunction
Vulvovaginal dryness
Spontaneous penile erection
Organic erectile dysfunction
Psychogenic erectile dysfunction
Orgasmic sensation decreased
Painful erection
Female sexual dysfunction
Male sexual dysfunction
Hypogonadism

Disturbance in sexual arousal
Secondary hypogonadism
Libido disorder
Erectile dysfunction
Genital pain
Female sexual arousal disorder
Genital discomfort
Genital hypoaesthesia
Painful ejaculation
Genital paraesthesia
Genital hyperaesthesia
Spontaneous ejaculation
Genito-pelvic pain/penetration disorder
Persistent genital arousal disorder
Genital dysaesthesia
Post 5-alpha-reductase inhibitor syndrome
Genital anaesthesia
Testosterone deficiency syndrome
Progesterone deficiency

Supplementary table 2. Dechallenge/rechallenge and causality assessment with esomeprazole and omeprazole.

	Esomeprazole		**Omeprazole**
	Genital discomfort	**Oestrogen deficiency**	**Erectile dysfunction**
	Females **N= 5**	**Females** **N= 3**	**Males** **N= 284**
Dechallenge			
Positive, n (%)			61 (21.5)
Negative, n (%)			14 (4.9)
Rechallenge			
Positive, n (%)			8 (2.8)
Negative, n (%)			1 (0.4)

Supplementary table 3. Number of comedications reported in the ICSR generating a potential sexual dysfunction-related safety signal, stratified by proton pump inhibitors and sex

Male sexual dysfunctions		
		Omeprazole (N= 385)
Erectile dysfunction	**N. Cases (%)**	284
	ICSR reporting co-medications associated with SD, N (%)	77 (27.1)
Female sexual dysfunctions		
		Esomeprazole (N= 42)
Genital discomfort	**N. Cases (%)**	5
	ICSR reporting co-medications associated with SD, N (%)	4 (80.0)
Oestrogen deficiency	**N. Cases (%)**	3
	ICSR reporting co-medications associated with SD, N (%)	0 (0.0)

Abbreviations: ICSR = individual case safety report; SD = sexual dysfunction